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THE COMPLEX WEB OF PRESCRIPTION DRUG PRICES, PART II: UNTANGLING THE WEB AND PATHS FORWARD

HEARING

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C O N T E N T S

THE COMPLEX WEB OF PRESCRIPTION DRUG PRICES, PART II: UNTANGLING THE WEB AND PATHS FORWARD

THURSDAY, MARCH 7, 2019

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 10:03 a.m., in Room 138, Dirksen Senate Office Building, Hon. Susan M. Collins, Chairman of the Committee, presiding.

Present: Senators Collins, Tim Scott, McSally, Braun, Rick Scott, Casey, Blumenthal, Warren, and Sinema.

OPENING STATEMENT OF SENATOR SUSAN M. COLLINS, CHAIRMAN

The CHAIRMAN. The hearing will come to order.

Good morning. Yesterday, this Committee heard the painful, personal stories of five people who struggle to obtain the medications they need at the prices they can afford. Their stories are familiar to far too many Americans who walk into the pharmacy to pick up a routine refill, only to walk out empty-handed, unable to pay the rising cost.

Some are tapping into their retirement funds or refinancing their homes, working multiple jobs, or living in endless uncertainty and anxiety about what the next month might bring. This should not be the experience of buying prescribed medications in our Nation.

The problems consumers have in affording prescription drugs add to the stress that they already feel as they cope with their illnesses.

We have a chart, which I am displaying, that I will defy anyone to figure out. It illustrates just how opaque and complex the drug pricing system is.

In this Committee's continuing effort to untangle this complicated web of prescription drug prices and to identify realistic, workable solutions, today we will consult with a panel of experts to look behind the scenes.

Each of the stakeholders in the health care supply chain plays a role, and we all must work together to bring down costs.

Combating high prescription drug prices has long been a priority for our Committee. Four years ago, we led a year-long investigation into the causes, impacts, and solutions to the egregious price spikes for certain drugs that had gone off-patent.

We released an extensive report, and I am pleased that several of our recommendations are now law. Today, these laws are helping to increase generic competition and improve transparency, but we still have so much more to do to produce lower drug prices.

In addition, last fall I developed bipartisan legislation with then Senator Claire McCaskill that prohibits gag clauses, an egregious practice that concealed lower prescription drug prices from patients at the pharmacy counter.

This legislation banning gag clauses is now law, so that pharmacists can help ensure that consumers are not paying more than they have to for the drug they require. Whoever would have guessed that in some cases it is cheaper to use your debit card than your insurance card to purchase a prescription drug? That is so counterintuitive that consumers would never think to ask that question of their pharmacists. Now the pharmacists can volunteer that important information.

Last Congress, this Committee also held a hearing to uncover the causes of soaring insulin prices, despite the fact that insulin has been available for nearly 100 years.

Through that hearing and a series of inquiries to drug manufacturers, pharmacy benefit managers, and insurance companies, I found that while manufacturers set the list prices, there are also other supply chain factors, such as the rebates paid by drug companies to PBMs and insurers, which play a significant role in driving up costs to the consumer.

The system appears to be characterized by perverse incentives and conflicts of interest that encourage higher prices.

The administration recently released a proposed regulation on rebates, and I am working with colleagues on both sides of the aisle to see what action Congress can take to ensure that any discounts actually translate to reduced costs for consumers at the pharmacy counter. That is not now the case.

Our Committee has also held a hearing to examine the opaque patent system that protects many of these high-priced drugs. We uncovered the use of patent thickets and so-called "evergreening" strategies that extend monopolies on blockbuster drugs for far longer than Congress ever intended when it gave the patent protection in order to encourage investment in groundbreaking drugs.

For example, Humira, the world's best-selling drug, is protected by more than 130 patents, some of which have terms that extend to 2034. These patents block generic competition that could bring down the price for biologics.

This week, I introduced the bipartisan Biologic Patent Transparency Act, a bill that would help make patents work as Congress intended. The bill would shine a light on disturbing patent strategies and deter companies from introducing patents late in the game in an attempt to prevent lower-priced alternatives from coming to market.

By addressing patent strategies that hinder true innovation, this legislation, I hope, will pave the path for new lower-cost alternatives.

High drug prices and cost increases that dominate our headlines and devastate our bottom lines are unsustainable for America's consumers.

In 2017, brand-name prescription drug prices increased four times faster than the rate of inflation. The time to act is now.

Today, we will examine ways to empower consumers, improve transparency, and fundamentally change the incentives in our broken system.

Navigating the prescription drug landscape is difficult, even for an individual with a graduate degree in the field. It should not take a Ph.D and an infinite amount of time and patience to figure out how much a prescribed medication will even cost the consumer.

I want to thank all of our witnesses for being here and for sharing their expertise on this problem with the Committee. I look forward to our discussion, and I turn now to Ranking Member Senator Casey for his opening statement.

OPENING STATEMENT OF SENATOR ROBERT P. CASEY, JR., RANKING MEMBER

Senator CASEY. Thank you, Chairman Collins. Thanks for having this hearing and yesterday's as well.

We want to thank our witnesses and everyone who is here.

We are grateful that for the second day in a row. we can focus on a critically important issue that so many Americans are not just concerned about, but are indeed burdened by.

As Chairman Collins mentioned, yesterday we heard very compelling testimony about the prices families must pay to purchase life-saving and life-sustaining medications.

Unfortunately, these experiences are all too common. There are policies that we can enact into law that will allow people to focus on getting well instead of worrying about their pocket books. Today, we will discuss some of those solutions. Yesterday, we heard about many of the challenges. Today, we want to focus on solutions.

We are long past time, though, for discussion. Individuals and families are both demanding and deserving of action by the U.S. Congress.

Today, for example, I am introducing two common-sense pieces of legislation to address the cost of prescription drugs. The first, of course, is with Chairman Collins, a bill to ensure that the cost of prescription drugs, especially the highest-priced drugs, are posted publicly for everyone to see.

The Obama administration started this practice in 2015 with the creation of Drug Dashboards. The Trump administration took action last year to update and expand on this information.

This bill that we are introducing would guarantee that information about drug costs in Medicare and Medicaid are posted every single year. Shining a light on the cost of these drugs is a critical first step in order to spot trends, to identify problems, and to find solutions.

The second bill that I am introducing would help seniors and people with disabilities living on less than about $25,000 afford their prescription drugs. One in four people on Medicare live on incomes below $15,250 dollars—one in four on Medicare.

My bill would help more people qualify for assistance, building on important policies passed in the Affordable Care Act. It would

also give more help to seniors who still struggle to afford high coinsurance rates and out-of-pocket costs.

This bill is modeled after an innovative Pennsylvania program known by the acronym P-A-C-E, PACE. This is a bipartisan program supported literally decades by both parties in Pennsylvania and Governors in both parties.

Yesterday, our witness, Barbara Cisek, spoke about how much it helped her mother when she was taking care of her mother when her mom had ovarian cancer.

By helping more people afford the cost of their drugs, it is my hope that we will hear fewer stories about seniors splitting their pills and more stories about, in fact, the way they live, and their grandchildren, and the like.

This is not all that must happen, though. We must do more. Congress, I believe, should also pass—in addition to the bills that I have mentioned and the work that Senator Collins has joined—pass legislation that would allow the safe importation of prescription drugs. I have introduced legislation with Senator Sanders to do just that.

Also, in addition to that, we must finally allow Medicare to directly negotiate, negotiate for the price of drugs, a policy that I have been supportive of since my first year in the Senate.

We must also seriously examine all of the proposals by the Trump administration aimed at reducing prescription drug costs. That does not mean we will all agree, but we should closely examine those ideas.

The Aging Committee has historically been an incubator of thoughtful policy, and I think that is true today as well. Drug pricing policy is one of the most complicated, as the chart indicates, that we will examine.

I am pleased that we are holding this hearing today and look forward to moving our policy discussion into action during this Congress.

Thank you Madam Chair.

The CHAIRMAN. Thank you very much, Senator Casey.

I also want to welcome and acknowledge that Senator Rick Scott of Florida is here today. He has a wealth of knowledge and information about health care, and I am very pleased that he could join us this morning.

I also know that Senator Warren intends to come back, if she can, and I expect others will be joining us as well.

I would now like to turn to our panel of witnesses. We are first going to hear from Lisa Gill who is the deputy editor of Special Projects at Consumer Reports. I am a longtime fan of Consumer Reports. I never buy a vehicle without checking with Consumer Reports. It now appears that I should never purchase a prescription drug without checking with Consumer Reports.

Ms. Gill led the Secret Shopper investigation and is also part of the organization Choosing Wisely and Preventing Over-Diagnosis Campaigns.

Our second witness, Pooja Babbrah, is the Practice Lead at Point-of-Care Partners. She will testify about technologies and tools that assist patients in securing the prescription drugs they need at the lowest possible cost.

Next, we will hear from Dr. Stacie Dusetzina—did I do it right?—who is an associate professor of Health Policy at Vanderbilt University Medical Center. She is also an author of the 2017 National Academy of Sciences Engineering and Medicine Report entitled "Making Medicines Affordable" and a brand-new article on the prescription drug pricing challenges that was just published in the Journal of the American Medical Association, so that literally is hot off the presses, and we are very delighted to be the first Committee to spotlight your research in that area.

Our final witness on the panel today is Jane Horvath, the principal at Horvath Health Policy. She, too, is an expert in this area and will discuss State efforts to advance transparency for prescription drugs.

I thank you all for being here today, and we will start with Ms. Gill. Thank you.

STATEMENT OF LISA GILL, DEPUTY EDITOR, SPECIAL PROJECTS, CONSUMER REPORTS, YONKERS, NEW YORK

Ms. GILL. Good morning. Thank you so much for having me here today.

Chairman Collins, Ranking Member Casey, and Committee members, we appreciate the opportunity to be here today to discuss the findings of our recent special investigation on the costs of drugs for seniors covered by Medicare Part D plans.

I speak to you today as a journalist who has had the honor and actually truly a dream of working for a decade on behalf of consumers at Consumer Reports. My work has focused on health care and specifically looking at consumer drug costs.

Consumer Reports is an 80-year organization. It is an 80-year-old, independent, nonprofit member organization. As you point out, we test cars and refrigerators and microwaves, and we rely on evidence-based testing and ratings, rigorous research, hard-hitting investigative journalism, public education, steadfast policy action on behalf of consumers' interests, and that is exactly why last summer when we noticed a small study coming out from researchers at Yale School of Medicine that suggested some medications might be less expensive if a senior decided to not use their prescription-—their Part D plan, and so we decided to take a closer look.

We wanted to replicate what a consumer would experience when they sign up for a Medicare Part D plan for the plan year 2019. We often use Secret Shoppers as part of our investigation, and it actually really is an approach to gathering retail prices of medications.

We gathered a list of five common generic drugs, and that included generic Lipitor, generic Celebrex, generic Cymbalta, generic Actos, and generic Plavix. These are typically fairly low-cost drugs.

Then we selected six mid-sized cities in the United States to run this test: Seattle, Denver, Des Moines, Dallas, Pittsburgh, and Raleigh.

Then we chose a ZIP code in each of those that was close to the city's center.

We logged onto the Medicare.gov website, and we used the Medicare Plan Finder Tool, just like any other consumer would, and we entered the five drugs in each of the ZIP codes, and then we se-

lected the three least expensive plans that we wanted to really look at.

Then we compared what a consumer would pay with the three low-cost plans with two different pharmacies in that ZIP code, and this is important because there is a lot of pharmacies in ZIP codes, but you can only compare two at a time.

Needless to say—and one of the reasons I am here—is because we did not expect to find what we did. Instead of identifying medications that might be less expensive if you skipped using your Part D plan, we found that what consumers could pay for their medications could vary by hundreds of dollars, and worse, if you made a small mistake while signing up, it could cost a consumer thousands of dollars.

Here are three quick examples. I will draw your attention to Slide 1, please.

If you accidentally forgot to enter one of the drugs into the Plan Finder Tool, it could be extremely expensive. We deliberately left off one drug. We signed up with a plan with four drugs, and the most egregious example was coming out of Des Moines. The annual drug cost for four drugs came to $407, which is actually a pretty good price, and that was with a plan called Cigna-HealthSpring Rx Secure-Essential, which sounds very promising until you add the fifth drug, which is, in our case, we left off generic Celebrex.

When you add that drug, the plan price, as you can see, jumped to $2,948, which is an astonishing amount. What we learned is that that drug was actually not covered by the plan, and not only that, they would charge a consumer $212 a month for that drug.

Just even before I came to this hearing, I wanted to double-check, just to see how much it would cost. I went to GoodRx.com, which is a very common discount website that we suggest consumers try. I found that drug for $16 at Costco-—$16, not $212—or $6 at Kroger, so if you think about that, that is crazy.

The second thing that we found—this is Slide 2—if a consumer picked a pharmacy that is simply convenient, they could wind up spending a lot more money.

Our example comes out of Denver. The total cost of the five drugs that we tested at a Walgreens was $1,687, not a great price, but it was okay, but 4 miles away in the same ZIP code, same plan, same drugs, at Cherry Creek Pharmacy, which is an independent pharmacy, the total cost for the year was a mere $688, nearly three times less expensive.

The third thing that we found—and this is for Slide 3. This is a general slide just showing the price variation in the six cities, but we learned too that if a person focused only on the deductible amount, they could overlook much cheaper plans.

Our example comes out of Dallas, one plan with a low $100 deductible, and I will remind the Committee that a deductible is the amount that a consumer must pay before the insurance kicks in. That $100 deductible plan would actually cost a consumer $1,592 for the entire year for those five drugs, but another plan in the same area with a $415 deductible would actually cost a person just $574, which turns out to be a pretty good price.

These results helped us formulate some consumer tips, but there were three quick specific problems I would like to point out to the Committee.

First off, it was very difficult to untangle how well any drug was covered by the Part D plan.

The second thing is that these preferred pharmacy agreements between a store and a plan meant that—this is what generates these insane price differences within the same ZIP code, and by the way, it was extremely difficult to tell when you were signing up for a plan which is actually the preferred pharmacy. It disappears as you go through the tool.

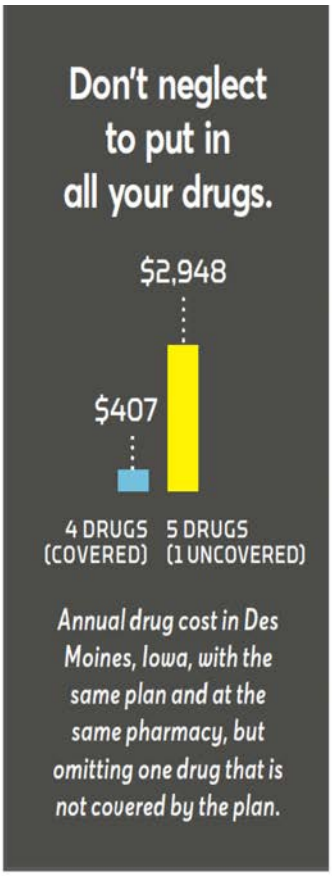
Then the third and final thing is that having a preferred pharmacy could mean that your favorite pharmacy in your ZIP code, where you have had a relationship with those pharmacists for many years, could charge for the same five drugs two wildly different rates with two plans, and our example again comes out of Denver, five drugs, same pharmacy, one plan, $524; another plan, $1,686.

It is clear that it is essential for consumers to have clear, comparative, easy-to-understand information, and we are pleased this Committee is looking at the topic.

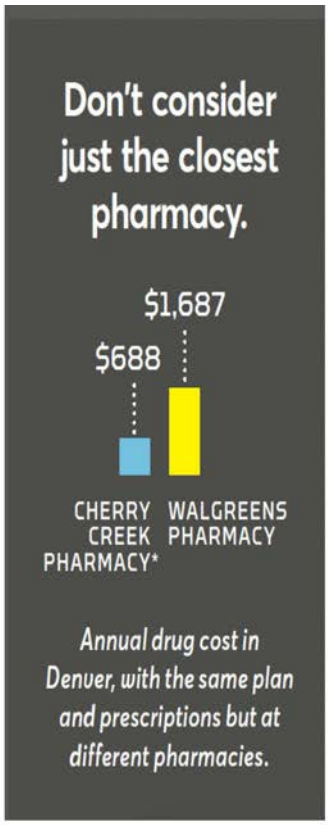
Thank you again for the opportunity to testify on this important issue for consumers.

[See slides 1-3]

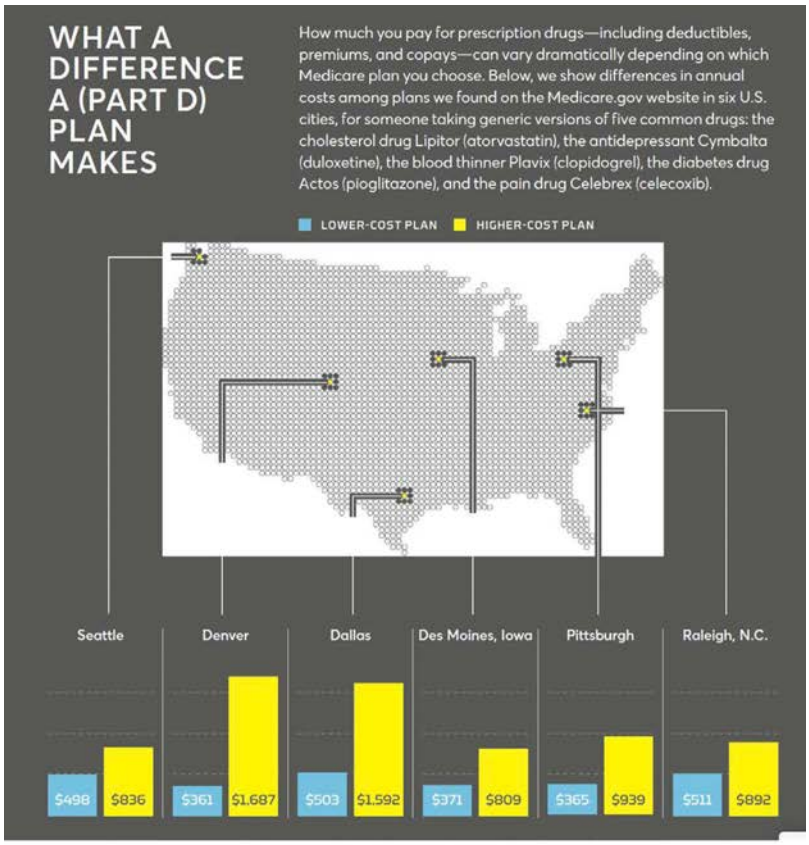
SLIDE 1


Don't neglect to put in all your drugs.
$2,948
$407
4 DRUGS (COVERED)
5 DRUGS (1 UNCOVERED)
Annual drug cost in Des Moines, Iowa, with the same plan and at the same pharmacy, but omitting one drug that is not covered by the plan.

SLIDE 2


Don't consider just the closest pharmacy.
$1,687
$688
CHERRY CREEK PHARMACY*
WALGREENS PHARMACY
Annual drug cost in Denver, with the same plan and prescriptions but at different pharmacies.

SLIDE 3


WHAT A DIFFERENCE A (PART D) PLAN MAKES
How much you pay for prescription drugs—including deductibles, premiums, and copays—can vary dramatically depending on which Medicare plan you choose. Below, we show differences in annual costs among plans we found on the Medicare.gov website in six U.S. cities, for someone taking generic versions of five common drugs: the cholesterol drug Lipitor (atorvastatin), the antidepressant Cymbalta (duloxetine), the blood thinner Plavix (clopidogrel), the diabetes drug Actos (pioglitazone), and the pain drug Celebrex (celecoxib).
LOWER-COST PLAN
HIGHER-COST PLAN
Seattle
$498
$836
Denver
$361
$1,687
Dallas
$503
$1,592
Des Moines, Iowa
$371
$809
Pittsburgh
$365
$939
Raleigh, N.C.
$511
$892

The CHAIRMAN. Thank you so much for a truly fascinating presentation.

We will now go to our next witness, Ms. Babbrah.

STATEMENT OF POOJA BABBRAH, PRACTICE LEAD, POINT-OF-CARE PARTNERS, PHOENIX, ARIZONA

Ms. BABBRAH. Thank you so much. Ms. Chairman, Ranking Member Casey, and distinguished members of the Committee. Thank you for inviting me to testify today.

My name is Pooja Babbrah, and for over two decades, I have worked in the health care technology industry, primarily focused on ePrescribing and eMedication management. I am currently a senior consultant with Point-of-Care Partners, the leading management consultancy focused in this space, and we have been working on real-time pharmacy benefit checks since 2014.

We are here today to talk about prescription price transparency, and I will focus my comments specifically on the real-time pharmacy benefit check transaction. For your reference, I have included historical context and technical details in my written testimony.

Now, I have been around long enough to remember the early days of ePrescribing, back in the late 1990's, and we have certainly come a long way since then, with availability of electronic tools and the information to help prescribers choose the most effective, appropriate, and cost-effective medication, but there is still key missing information at the point-of-care.

The real-time pharmacy benefit check transaction is really in response to prescriber challenges of the benefit information that is being provided in the electronic health record today. Real-time pharmacy benefit check helps fill an information gap around transparency, but its value goes far beyond that.

The transaction, its standards being developed by NCPDP, the preeminent ANSI-accredited standards development organization for prescription transactions in the ambulatory, long-term care, and post-acute care settings. The transaction can actually provide crucial information to facilitate conversations between the physicians and their patients around their medications.

Now, this can include patient out-of-pocket cost, any alternative medications that may be more affordable for the patient, the best place to fill their prescription, and also insights into additional requirements that may be required, such as prior authorizations.

The goal around this is to provide more accurate information about the patient's prescription coverage and the cost of their medication in the physician office as opposed to having the sticker shock at the pharmacy counter.

Studies have shown that cost is the No. 1 reason that patients are abandoning their prescriptions and not adhering to their medication treatments. In other words, the provider prescribes the medication, but the patient does not fill the prescription, or the patient fills the medication and then only takes a partial dose because it is too expensive to get a refill, and we heard some of those stories yesterday from the patient testimoneys.

Now, both of these scenarios will likely lead to greater health care cost down the road, leading to additional office visits, unwanted ER visits, and potential hospitalization, but by providing

insights into the cost of the medication to the prescriber, we believe that real-time pharmacy benefit check will enable prescribers to ensure that the prescriptions that are written actually get filled and the patients are taking them as prescribed, which will in turn lead to greater public health.

Now, there are a few shortfalls with the real-time pharmacy benefit check as it is being employed today, including the lack of information about potential cost savings, discount programs, and other financial support programs.

It is also important to note that the transaction only provides the pricing on a patient's pharmacy benefit, not their medical benefit, and often expensive specialty medications are actually covered under the medical benefit, and the real-time pharmacy benefit transaction will not show that pricing.

Use of the real-time pharmacy benefit check is also somewhat limited in scope today. It is primarily used by prescribers through their electronic health records, and we believe that it is important to expand the reach of this transaction to the patient and the patient care givers.

Finally, we believe the real-time pharmacy benefit check should be expanded to incorporate additional information related to patient out-of-pocket cost for the drug. Specifically, patients and their caregivers should have information that will help them determine whether they should obtain their medication under their prescription benefit or pay cash at the pharmacy.

Tremendous progress has been made with the development and utilization of the real-time pharmacy benefit check, but to date, the business cases have been focused on payers, PBMs, and the providers, and we are confident that widespread use of the transaction will yield a public health gain, while at the same time enabling patients to receive their medications at the lowest possible cost.

I thank you for the opportunity to testify today, and I would be happy to answer your questions.

The CHAIRMAN. Thank you very much, Ms. Babbrah. We very much appreciate your being here today.

Next, we are going to go to Dr. Dusetzina.

STATEMENT OF STACIE B. DUSETZINA, PH.D, ASSOCIATE PROFESSOR, HEALTH POLICY, VANDERBILT UNIVERSITY MEDICAL CENTER, NASHVILLE, TENNESSEE

Dr. DUSETZINA. Thank you so much.

Chairman Collins, Ranking Member Casey, and distinguished members of the Committee, it is my pleasure to be here today to testify on this important topic.

My name is Stacie Dusetzina. I am an Associate Professor of Health Policy and Ingram Associate Professor of Cancer Research at Vanderbilt University School of Medicine.

My research focuses on prescription drug policies that facilitate and impede the use of these important products for patients.

I also had the honor of serving on the National Academy of Medicine's committee on ensuring patient access to affordable drug therapies, and that report was published last year.

My research includes findings related to the role of drug rebates for increasing patient and taxpayer spending in the Medicare Part D program, how having higher out-of-pocket costs for patients is

associated with lower use of needed medications, and how prescription drug list prices and price increases have made many drugs unaffordable for Americans.

In the United States, many patients are facing the reality that prescription drugs are no longer affordable for them. Our work, for example, has shown that in the Medicare Part D benefit that it requires patients to pay a percentage of the drug's high list price for virtually all anti-cancer drugs. This means that patients will spend thousands of dollars out of pocket when they fill their first prescription.

Like Ms. Holt, who was here yesterday talking to the Committee, filling Revlimid, this drug costs the Medicare program $21,000 for a 28-day supply today, and it would cost a patient filling the drug for the course of a year over $15,000 out-of-pocket, and that is for only that one drug.

This high level of spending has also been shown across other disease areas for patients needing complex treatments.

Commercially insured patients are also exposed to high out-of-pocket spending, so this is not only a Medicare Part D problem. Deductibles and coinsurance, where patients pay the full price of a drug when they fill it or when the pay a percentage of the drug's list price, have become much more common in both commercial health plans and under the Medicare Part D benefit as well.

Under these arrangements, patients are being asked to pay based on a drug's list price, which can be much higher than the price that is paid by the PBM or the health plan itself.

As an example, a patient filling an 84-day course of hepatitis C treatment, a very important curative therapy, would have their out-of-pocket cost under Part D calculated based on a list price of $93,000. Instead, their health plan and PBM are likely to be paying closer to $35,000 for that same product.

Now, it would be beneficial to share that lower price with patients and have their cost calculated on the lower post-rebate price, but I argue that this would also result in a significant financial burden. Best-case scenario, patients paying on the $35,000 price would still have to pay out-of-pocket over $4,000 to fill that drug. I think that is very much unaffordable for many people.

Insurance should be designed in a way that protects people from financial catastrophe when they are sick, and today's Medicare Part D program does not do that. Instead, patients who need expensive drugs or who need a lot of drugs are exposed to unlimited out-of-pocket spending on the program.

Congress and the American public have heard and will continue to hear from stakeholders within the supply chain, and they all will point to one another as the key problems, but in fact, they are all part of the problem, and they all need to be part of the solutions. This is a complex area, so solutions are also going to be complex.

When considering solutions, I would recommend the Committee focus on three key goals. The first would be that we should ensure that patients have access to high-value drugs at a reasonable out-of-pocket cost for them. The second is to consider ways to remove incentives that are in the system for high list prices and price increases, and the third is to reward innovation, true innovation by pharmaceutical companies, by paying for value.

I thank the Committee for the opportunity to be here today, and I look forward to working with all of you on solutions and look forward to your questions.

The CHAIRMAN. Thank you so much for your testimony.

Ms. Horvath.

STATEMENT OF JANE HORVATH, PRINCIPAL, HORVATH HEALTH POLICY, WASHINGTON, D.C.

Ms. HORVATH. Thank you, Madam Chairwoman and Ranking Member Casey and members of the Committee. I really appreciate the opportunity to be able to talk about this complicated but very important topic today.

My name is Jane Horvath. I am currently a consultant, and I work pretty much exclusively with States, State legislatures, State agencies, and State national associations on describing the drug financing and supply system, so people can understand it, but then also on cost containment policies.

Specifically, I have worked with California, Nevada, and Oregon on their transparency implementation and/or—their legislation and/or their implementation.

Transparency is a really important first step in managing drug costs. Transparency has improved the policymakers' understanding of how things work and understanding what they still do not know how it works, but it is an opportunity to figure out how things should work.

States and the Federal Government have taken really important first steps, in my view. On the Federal side, CMS has the dashboards that Senator Casey referenced a minute ago for Medicare and Medicaid and even rebate information on Medicare, which I think is really important. CMS also has the National Acquisition Cost Data base, which is a great research tool for policymakers and researchers. There is nothing else like it that I know of.

For States, they have done transparency and are doing transparency on drug prices and drug price increases, transparency on insurer drug spending, net gross as a percentage of premium. It is all very interesting data, and more recently, transparency on the PBM business model and how that impacts the whole financing chain.

I tend to think of things as the supply chain and the financing chain, and it does untangle the web a bit and makes things a little clearer, so that is how I will discuss it today.

These have created really important discussions everywhere, but today, I advise States, if they ask me, not to pursue any further transparency legislation. We have eight States now with very good transparency legislation. Maine is implementing transparency legislation. Vermont has excellent legislation. Oregon and Nevada have good—and California. Almost everything that the States are collecting is going to be public.

I think States do not need to spend a lot of resources inventing these really complex data bases to capture and release this data, and I think that Feds can help States do more. I think it would be really interesting to ask the Office of Personnel Management for their plans to produce very similar data to what the States are producing—insurer, PBM, manufacturer.

I also think it would be really important in Medicaid to understand which drugs in the Medicaid program are rebating at just the Federal minimum. I mean, it is not a minimum, but the Federal floor, the rebate. I think that will tell us about drugs, where there might be deep discounting or not among some high-cost drugs. It will show us some consumer behavior without releasing any proprietary data, per se.

Then I think looking in Medicaid again, there is a cap in what a manufacturer's rebate liability is at 100 percent of really the market price, and they get to that cap basically after they have had a whole bunch of price increases, so even if you follow the formula to the end, the rebate might be 140 percent of the market price of the product. It is kept at 100, and I think it would be really interesting to know how many drugs and which drugs have reached that 100 percent cap in liability. That will tell us something about price increases I think industrywide.

I would like to very briefly move beyond transparency because I think transparency is the first step.

Federal law and Federal case law really do hamstring States in their ability to really affect consumer cost of prescription drugs, but there are a couple things that I think the Federal Government can do to really open up State financing innovation here, and one would be to expand the list of countries from which State programs can import drugs. This would certainly help Florida, since Florida's population is almost the size of Canada's. Clarify that patent law does not limit the State ability to regulate patented prescription drugs, and exempt from Medicaid best price, State programs, sort of large State cost control programs, innovative programs. In Q&A, I can explain why that would be important. Then, finally, just to uncap that Medicaid rebate liability that I described a few minutes ago.

That is it, so thank you.

The CHAIRMAN. Thank you so much for your excellent testimony.

Ms. Gill, I want to start with you. I thought it was so interesting as you went through your charts that not only is the choice of plan important, but also the choice of pharmacy, and I do not think most of us think about that the differences in price may occur at the pharmacy level as well, so that was really very illuminating.

I remember how shocked I was when a group of pharmacists in Maine came to meet with me and told me that in some cases, prescription drugs would be less expensive if the consumer did not use insurance. That just never would have occurred to me.

Based on your investigations of prescription drugs that seniors commonly take, could you give us some idea of how often you found that the price would actually be less paid out-of-pocket rather than using insurance?

Ms. GILL. Sure, so out of the 18 plans that we looked at across the United States, in total about 18 percent of the time, it would have been less expensive if someone went outside of their plan.

Now, what is important to note is that we actually do not typically recommend that because you really want that amount of money that you are paying to go toward your deductible, but it depends on where you are as you are reaching the doughnut hole.

The CHAIRMAN. That is amazing, but you are right. The downside is that it does not count toward your deductible.

Doctor, I want to talk to you about a comment you made about our need to remove the incentives for high list price. I am very intrigued by this because, as I look at the system, part of the problem is how pharmacy benefit managers are compensated, and if they are compensated through the rebate and as a percentage of the list price and the pharmaceutical company knows that the pharmacy benefit manager is going to make the decision of whether or not their drug is included in the formulary of the insurer, isn't that an incentive for the pharmaceutical manufacturer to keep the list price high?

Dr. DUSETZINA. Absolutely, so right now, there are incentives in that whole web that you projected earlier for everyone to have the list price be high.

So we have shown in our work that as the list price increases that it benefits the drug manufacturers. It benefits the pharmacy benefits managers and in some cases benefits the health plans because of the way that Part D is designed. It does not benefit the consumer, and it also does not benefit the taxpayers because most of the spending, once people have hit the catastrophic phase of the Part D benefit, is going to be paid by taxpayers through the reinsurance part of the benefit.

The CHAIRMAN. If you change the compensation for pharmacy benefit managers so it was fee-based rather than a percentage, would that help?

Dr. DUSETZINA. I think we need to move away from percentage-based payments for pretty much everyone in the supply chain, not just PBMs, physicians as well, but, yes, I think that that could help in some ways to just pay a flat fee for those services rather than paying based on the spread pricing or paying by percentage of list price. I think that would absolutely be a step in the right direction.

The CHAIRMAN. Ms.—I am sorry that I keep having trouble with your name—Babbrah.

Ms. BABBRAH. Yes.

The CHAIRMAN. I saw you nodding. Is that correct? Do you agree with that assessment as well?

Ms. BABBRAH. Yes. Well, I just think that the fee-based is—we need to start really looking at outcomes as opposed to actual fee-based pricing in my opinion.

I am here to talk about the technology, but I do agree with that statement as well.

The CHAIRMAN. Thank you.

Senator CASEY. Thank you very much.

I want to start with Ms. Horvath on the question of transparency. As I indicated earlier, at least implicitly, there is one thing, maybe only one thing, that the Obama and Trump administrations agree upon, and that is that the cost of prescription medication should be available of the public. That is the dashboard issue in legislation that I mentioned.

This started with that administration maintaining an online drug dashboard, including a snapshot of average spending for any given year and over time for hundreds of prescription drugs.

Obviously, we need to keep that updated every year. The legislation that Senator Collins and I are working on would ensure that no matter who is in the White House, we all have access to this information.

Just a basic question on this. Do you think that drug price transparency has and can impact the cost of prescription medication?

Ms. HORVATH. I do not think it does. I think what it does is inform conversations and discussions and policymaking about how then to constrain the cost of prescription drugs.

California had this—and Oregon and Nevada—they have very substantial bills on reporting price increases over a threshold and stuff, but manufacturers are reporting those price increases over those thresholds. They are not constraining themselves so they do not have to report.

Senator CASEY. Do you think the key is what to combine transparency with what?

Ms. HORVATH. Actually, I think there is only really a few ways to make sure that on the financial side, the transactions, the benefits of rebates and everything else get to the consumer at the point of service is a controlled importation program or—like I am working on with several States now setting all-payer upper payment limits, so, once you do that, you are able to watch and monitor for competitiveness in the system, watch and monitor for price increase, people taking margin, basically, on the price of the drug, and I think when you do that, then you can move more to fee-based, you know, paying people for their services by fees instead of percentage basis on the cost of the drug.

I wanted to just say one thing about eliminating PBM rebates. To the extent that the PBMs pass through those rebates to the health plan, that goes basically to offset the cost of the premium, so they do serve an important function, and to just shut that off means that premiums will rise because we do not necessarily know that the drug cost is going to go down, so I just throw that one caveat out there about eliminating rebates.

Senator CASEY. My next question, Doctor, our testimony yesterday on the cost as it pertains to individuals, we know that—and I focused a little bit in my opening about the one category of folks who are both seniors and low income. They are the most likely to face these difficult choices that we have talked about.

Some of the lowest-income seniors who have both—are both low income and have no savings can qualify for a Federal assistance program, which has been called—the vernacular is "Extra HELP" to cover some of those costs, but even with Extra HELP, high coinsurance costs or high coinsurance rates can put needed prescription drugs out of reach.

Can you tell us what your research shows about seniors who qualify for this so-called "Extra HELP program," but still struggle to afford their medications?

Dr. DUSETZINA. Absolutely. Thank you for the question.

One of my trainees has actually done some work on this area, and it is the first study that I am aware of in this space looking at individuals who qualify for the partial subsidy or Extra HELP, and what we found were that for people who were taking certain cancer treatments, that those who were in the Extra HELP pro-

gram actually did worse than people with no help or who had Medicaid.

When you look at the benefit, you can see why. Right now, the Extra HELP benefit asked people to pay 15 percent coinsurance for their drugs. Now, we were studying drugs that cost upwards of $10,000 per month, so you can imagine if you have very little savings, you almost qualify for Medicaid, but you do not, that you could find yourself being completely priced out of those important drugs.

Senator CASEY. Thanks very much. I know I am over time. Thank you.

The CHAIRMAN. Senator McSally.

Senator MCSALLY. Thank you, Madam Chairwoman. I appreciate you holding this hearing on this important topic. There are so many people in Arizona, seniors and others, that are really struggling to afford the prescriptions that are life-saving prescriptions, so I appreciate all the testimony today as we try and solve this issue.

There is one, for example, my team informed me of a lady named Jean who is a senior resident currently taking seven prescription drugs for various conditions, lives on $899 a month for Social Security, her only source of income. She has to cut back on food, cannot make repairs to her home, has no income left for anything else. She says the only way she can exist, if she runs up large debt on her credit cards. She has expressed she needs these drugs to live and cannot go without them. Increasingly, more and more seniors we see are having to choose between prescription drugs and their other payments for just surviving.

In Arizona, many people are then going to Mexico in order to get access to medication they need, and we have other reports. It has been reported in Arizona, 100 different medical practices have been implicated for black market supply chains with counterfeits that people are turning to because they cannot afford the drugs at the pharmacies.

There was a citizen of Arizona named Betty Hunter who had lung cancer, received a counterfeit infusion of a cancer-fighting drug, and in the end, the FDA found the medication contained water and mold. Ms. Hunter died a few weeks later.

This is what is happening to people because they cannot afford the medicines they need to stay alive. They either have to choose between food or their medicine or they have got to go to Mexico to get it or they are relying on counterfeit drugs. I mean, this is not acceptable, and I appreciate all of the discussion about what we need to do to bring down the cost of drugs, but then also make it transparent.

I know this is a complex issue, but why can't we have an expedia.com of prescription drugs? Even if you are trying to get it from a pharmacy, you can at least look at, when your doctor says which one should I send it to, and the answer is "I do not know. This one, this one, or this one," that you can actually look and see which one is going to be the cheapest for me and then send it there. What barriers do we need to just provide that basic transparency so people can shop around?

Anybody want to jump in on that?

Ms. BABBRAH. I will take that. The real-time pharmacy benefit check that we now can offer to physicians is currently available between the PBM and the physician in their electronic health record, but part of the issue with that is it is only giving you the cost under insurance.

Senator MCSALLY. Right.

Ms. BABBRAH. It is great information, and the work flow today is you do usually have a favorite pharmacy that you are going to, so when the physician checks that price, it is going to show you the price at that specific pharmacy under the insurance coverage, but we are actually working—there is an organization called the CARIN Alliance, which is a bipartisan organization that is looking to bring this real-time pharmacy benefit check to the patients.

Senator MCSALLY. Exactly.

Ms. BABBRAH. As we heard, the cash price may actually be better than what is covered under your insurance.

Senator MCSALLY. Exactly.

Ms. BABBRAH. You would be able to basically shop around, figure out that cash price, but then the other piece is if you pay cash at the pharmacy today, the insurance company may not know that, so we really need to be looking to close that loop because they may not know that you have actually picked up that medication.

Senator MCSALLY. We should be able to type in your ZIP code, just everything else we do, search within 10 miles, and then figure out what the cost is going to be, and let the patient choose whether they want to pay cash or have it go toward their deductible. This is all about patient choice, patient transparency, and competition so that they are able to afford their basic medicines.

Ms. GILL. I would underscore that by saying that based on the research that we have done as well as multiple other stories besides this investigation on Medicaid Part D plans, I would sum it up by saying that it is a game for consumers, and it is a terrible game.

Senator MCSALLY. Yes.

Ms. GILL. While I appreciate the concept of transparency, we have to have it. It is a function of being able to make a clear choice. At the same time, we are asking consumers to run around, check apps, look at websites, call pharmacies. The amount of administrative burden required to figure out what is the least expensive price—I mean, I make a career off trying to tell people——

Senator MCSALLY. Right.

Ms. GILL [continuing]. where to find it and how to do it, but, at the same time, the mechanisms in place to allow that are just that is what has run rampant. Whether it takes rules, laws, regulations to stop it is probably what will be needed.

Senator MCSALLY. What barriers do we need to remove? We do this for literally nearly everything else in our life? Type in your ZIP code, pull up the numbers, click on the one you want. What am I missing?

Dr. DUSETZINA. It is complicated because the consumer is not necessarily the one paying the largest part of the bill.

Senator MCSALLY. I know.

Dr. DUSETZINA. The insurance company has a role, and I think that is one thing that makes the technology so different is because you are trying to take into account all of these factors.

I think that the point of Consumer Reports, whose job it is to investigate these things, found it to be incredibly difficult to be able to find the drugs at the lowest price. I think it really highlights that we should have policies in place that make it pretty straightforward for people——

Senator MCSALLY. Exactly.

Dr. DUSETZINA [continuing]. make the drug that is preferred and cheapest for the plan, the lowest cost for the patient, and make it a low cost and predictable cost.

Patients are sick when they are searching out these drugs——

Senator MCSALLY. Right.

Dr. DUSETZINA [continuing]. and they do not probably want to spend all of their time trying to find the best deal. They want to just be treated and get well.

Senator MCSALLY. I agree. Thanks. I am over my time. Thank you.

The CHAIRMAN. Thank you.

Senator WARREN. Thank you, Madam Chair, and again, thank you for having this hearing.

According to a recent Kaiser Family Foundation poll, one in four Americans have difficulty paying the cost of prescription drugs, and 30 percent have skipped some of their prescription medications over the past year because of cost. Meanwhile, the drug companies that make the drugs, the insurance companies that are supposed to help pay for them keep raking in record profits. Families are the ones who are paying skyrocketing cost.

Now, as Senator Casey discussed, we need to tackle out-of-pocket Medicare—cost for out-of-pocket Medicare beneficiaries, but out-of-pocket costs were also a problem for patients with private insurance, and I hear all the time from constituents who have private insurance, but who are still struggling to pay for their prescriptions.

Ms. Gill, if a patient is taking a drug and wants to shop around for an insurance plan to make sure that she picks the one with the lowest out-of-pocket cost for that particular drug, is it easier for her to get accurate information?

Ms. GILL. I am going to make this answer really short. If she has an employer, she is not able to shop, typically, so she has given a—she may have an option between health insurance plans, but typically, they roll up into a single pharmacy benefit.

Senator WARREN. Oh, interesting. Okay.

Let us say she is in a private market, so she is looking in the marketplace. She is in an ACA marketplace, whatever it is. She is in a marketplace, and she has picked a plan that looks like it is the lowest copay on a drug she needs. Is the insurance company prohibited from changing that drug's copay after she has enrolled in the plan?

Ms. GILL. In 46 States, they can do whatever they want.

Senator WARREN. Okay.

Ms. GILL. A consumer is at the mercy of those plans.

Senator WARREN. The shopping is hard to begin with, and in some places, you cannot even shop. Even if she can shop, they can change it after she has purchased.

Ms. GILL. Absolutely.

Senator WARREN. We know that the insurance company might jack up the cost of the drug, maybe because the drug company increased the price or maybe just because the insurance company felt like it, but at least, will the insurance company have to keep covering the drug?

Ms. GILL. In Texas, yes, which is——

Senator WARREN. We have a lot of States.

Ms. GILL. Right, but that is really the—there are a couple—and anyone else who is an expert here, Jane maybe, on State law, it varies by State, but typically no. A consumer truly is at the mercy of what a pharmacy benefit manager is going to do.

When we use the term "jack up the price," what we really mean is they can decide to drop coverage of the drug altogether. They could decide to move it on a tier. Most consumers do not really even understand what "tier" means. I think that is one of the problems, so the consumer is also not able typically to shop around afterwards looking for another plan, so they are locked in for the year.

Senator WARREN. Even this highly motivated patient who really puts a lot of energy into shopping——

Ms. GILL. Right.

Senator WARREN [continuing]. the answer is she has multiple ways she could get stuck at the end of the day——

Ms. GILL. Absolutely.

Senator WARREN [continuing]. with very high copays.

Dr. Dusetzina, let me just ask. How does it impact patients when the copay on a drug rises midyear or a drug gets dropped from coverage?

Dr. DUSETZINA. We know from a lot of research that when patients face a price shock, so when their price goes up suddenly, that a lot of them will walk away without filling their prescription drug, or they may take less than they should, so we know that this happens. In fact, this has been studied quite rigorously under the old version of Medicare Part D where we had the doughnut hole, where you would see patients hitting this high out-of-pocket spending at one point in the year, and they would just quit taking their drugs until the beginning of the next calendar year.

Senator WARREN. All right.

Dr. DUSETZINA. It is very bad for patients.

Senator WARREN. The drug companies keep jacking up the prices. The insurance companies keep shifting the coverage so that more of the cost goes over to the patients. System works great for everyone except families who either go without appropriate care or sink into debt.

We got to tackle these problems head on. Now, I am going to be reintroducing my Consumer Health Insurance Protection Act, which cracks down on a whole list of shady insurance company practices that they use to avoid covering prescription drugs.

Two of the provisions in the bill I am reintroducing are capping out-of-pocket drug costs at $250 a month for individuals and $500

for families and banning insurance companies from dropping a drug in the middle of the year, not just in one State, but nationwide.

This just seems to me this is the moment we have got to be putting patients first, and that means putting an end to the greedy practices of insurance companies that are leaving patients without the coverage that they thought they were getting.

Thank you. Thank you, Madam Chair.

The CHAIRMAN. Thank you.

Senator BLUMENTHAL. Thank you, Madam Chairwoman. I want to begin by thanking you and Ranking Member Casey for bringing the issue of prescription drug cost before the Aging Committee again. It is a subject that we discussed before and rightly deserves our attention again.

This issue is of paramount importance, particularly to seniors in Connecticut and across the country. Drug prices are far too high and rising even higher, and what strikes me is how little we have succeeded in doing about it.

Last week, I reintroduced the CURE—C-U-R-E—High Drug Prices Act, which would hold pharmaceutical drug companies accountable for price increases that are unjustified by any cost increases and would provide a mechanism to oversee those prices, so that the Department of Health and Human Services could limit them to 10 percent a year, 20 percent over 3 years, 30 percent over 5 years, unless there were some fact-based justification for them.

I know that kind of price restraint mechanism sounds draconian, particularly to people who believe in the free market. I believe in the free market, but I think we have reached the point where we need to send that kind of message.

I know that Senator Casey asked a little bit earlier whether transparency alone could bring down prices, and I understand that and thank him for raising that issue very directly.

I would like to ask Ms. Horvath whether—and the other members of the panel whether you agree that this kind of action may be necessary to bring down drug prices, more than just transparency.

Ms. HORVATH. Your bill that you have dropped in, yes, I think it will. Almost by definition, it will.

The one thing, then, it has always seemed to me that if you are going to focus on price increases, you also then have to focus on launch prices because a company who understands that their capacity over the patent life of the product to increase the cost over that patent life is going to be limited is going to front-load and produce a higher launch price, so that is the tradeoff.

Senator BLUMENTHAL. That is a really, very good, and important point, and I see you are nodding, Ms. Dusetzina.

Dr. DUSETZINA. Yes, that is right. I think that is exactly right.

I do also applaud the idea of being able to use transparency efforts to understand real drug price increases and thinking about how to try to limit those price increases, but completely agree that if you put a signal out that you are going to start clamping down on drug price increases then and not doing something about launch prices, you will end up in probably a same or worse position.

Senator BLUMENTHAL. Any other members of the panel have thoughts about that issue?

Ms. GILL. I will say Consumer Reports, I believe, is on the record. The advocacy arm of Consumer Reports is supporting the CURE bill.

Senator BLUMENTHAL. Right.

Ms. GILL. I think that would be important. Transparency goes a long way for everybody and certainly for consumers.

Senator BLUMENTHAL. Let me just ask in the minute I have left. Do you have any thoughts about the launch price issue, how best to achieve transparency and some constraint on the levels of pricing?

Ms. HORVATH. Manufacturers properly, to some degree, focus on the value of their drugs, and most drugs are really invaluable to the quality of a person's life or even their life writ total, but they are not affordable, and I think we need to start making a distinction between affordability and value, and I think we need to move the discussion to affordability and away from value because there is lots of things in life that are invaluable to—like clean water, but it is affordable for people to be able to pay their water bill in most cases. We need to start thinking more in those terms.

Senator BLUMENTHAL. Yes. I might, just in conclusion, say what concerns me is not only the launch but, in a sense, the relaunch, where the patent process may be abused, and an old drug may be put in a pill of a different color and a new patent obtained and thereby generics kept off the market and prices increased. I know this is a vast oversimplification, but I think it is a real problem.

I want to thank the witnesses and thank you, Senator Collins, Senator Casey.

The CHAIRMAN. Thank you.

Senator BRAUN. Thank you, Madam Chair.

Transparency is one thing. Actually, the people that use the system embracing that transparency is another thing.

Ten years ago, when I took on the whole gamut, not just prescription drug prices, but basically health insurance being so paternalistic and giving us so few tools to use, I can tell you it took a radical system change within my own company, with a little bit of wishful thinking to make sure it was all going to work.

We set the stage for using the meager transparency tools that were available, but trying to create a culture where we emphasized prevention, not remediation, and just engagement among my employees and their own well-being.

We basically, in the process of trying to find that transparency, which was so opaque 10 years ago—we actually were able to, but it took a little bit of coaching and encouraging through some skin in the game among our employees before they really looked hard because, with low copays—and any of the panel, I would love to hear your thoughts on this—which keep skin out of the game, how do you get—make that big jump to where if you do have transparency, that you can even get the people using the system with copays to use it? We could not really get much traction on lowering health care costs until we crossed that big divide, and when we did, things started cascading to where we started saving a lot of money.

How do we get a paternalistic system to the people that have been using it to embrace transparency when you have got things like copays? Any of the panel that would feel comfortable answering that.

Ms. BABBRAH. I think the first step in that is just helping the patients understand and the caregivers understand even what they are going to pay.

I think we heard yesterday just a lot of confusion about how I get to the pharmacy and I do not even know what I am going to pay that month.

I think part of it is just giving the tools to the patients and the caregivers to even understand what they are going to be paying out-of-pocket, and once you do that, then you can start maybe putting in some of those incentives or things that will actually get them more skin in the game.

I think at this point, there is just so much confusion out there that you are not even going to get to that point that you want to get to yet.

Senator BRAUN. Most plans do have copays. If a copay is only $10 or $20, do you think they will even make the effort of trying to shop around?

Ms. BABBRAH. I think at that price, maybe it is not worth it, but I think we are hearing enough, and with more of the specialty medications that are coming into the market, you are seeing more and more of those copays. You are also with the high-deductible plans. I mean, even when you have a low copay, it is not necessarily—to me, I think the plans have changed enough that you are not even seeing those low copays anymore, just because of so many of the high-deductible plans that are out there.

Senator BRAUN. Okay.

Dr. DUSETZINA. You know, one of the things that you could do as an employer are things like reference pricing, which is a strategy that is being used in some cases to say you as the employer or insurance company have picked a low-priced product for you as the preferred drug. You set that cost really low for the patient, and then the other choices are much more expensive, so it really helps to align what patients are doing with what is the lowest cost for the health plan and hopefully the highest value overall, so that is something that has been tested and is being shown to work in some employer-sponsored benefits, for example.

Ms. GILL. I would love to say, too, shopping around it not necessarily the actual goal. It is indicative of a problem. It is a symptom of an illness in our system.

We, as reporters, try to help people find ways to shop, but it is only a workaround to a really terrible problem.

The issue, you are asking about copays, and to the point of the skin-in-the-game concept, when I hear that, what I hear is an insurance company or a PBM pointing a finger at you telling, "You guys are using us too often." My advice actually to any employer would be to turn around and go back and say there are three, four, or five provisions that we want to see you be better for. We want you to be a fiduciary for us. We want you to help us, not just simply put it back onto an employee's—truly, they are a burden, an

administrative burden and also a shopping burden, to try to figure out what is the best deal that this insurance plan has offered.

Senator BRAUN. That is a great point. I am out of time here, but during that whole journey, I have been talking about the industry itself. If they want to save themselves from one business partner, the Federal Government, they better get with it.

I would admonish anybody in the health care business to start being proactive, do these things, so it is not so difficult for all of us, whether you are through Government-paid health care and especially the private arena. Get with it.

Thank you.

The CHAIRMAN. Thank you very much, Senator.

Ms. Horvath, at yesterday's hearing, we heard from witnesses who were having trouble affording the best treatment for their individual health care needs. One witness was prescribed a PCSK9 inhibitor, and similar to 75 percent of Medicare beneficiaries who are prescribed that, she could not fill it because of the high out-of-pocket cost.

Another witness with type 1 diabetes from my home State of Maine could not afford the continuous glucose monitor and pump that she needed to keep her diabetes under control.

Now, the irony and tragedy here is the woman from Maine was ending up with costly monthly emergencies. She was going into—she was literally falling unconscious while driving because of low blood sugar. She had repeated hospitalizations, all of which cost the insurer more than if they had paid for her continuous glucose monitor and pump, which would have prevented these terrible incidents.

I know that some insurers are experimenting with value or outcomes-based contracting. Can you give us any assessment of what those arrangements have produced so far? How can we solve this problem of insurers being unable or unwilling to pay for essential treatments, and yet they will end up paying more for hospitalization to have results?

Ms. HORVATH. The question of value-based contracting, I think the jury is still out on that. I personally—and I do not think I have a widely shared view here, but again, I personally think that when you start talking about value, you are really—you are in the manufacturer's ball game because their drugs are highly valuable or invaluable, so I worry about that.

In terms of how these value-based contracts have worked out so far, I do not think we know. Most of the contracting is pretty proprietary between the manufacturer and the State. I am looking at State Medicaid agencies that are doing this.

The only thing I would say is that years ago—and not that many years ago, like 15 years ago, there were no drug deductibles. Drugs got first dollar coverage under your insurance benefit. Like we did not have any of the zooey-ness. It is because prices—It is insurers trying to manage the prices, and, you know, insurers know that that is dumb, what you just described, and almost nonsensical, except for the fact that that just then gives the manufacturer free rein to increase the price of their stuff twice a year, three times a year. It is limitless.

Again, insurers know that this is a crazy system and that beneficiaries suffer, and pharmaceutical manufacturers do and device manufacturers do. They built their model on price instead of units sold. It has been a whole shift in the industry in the last 15 years.

Their profit structure is built on the price of the product, now how many bits of the product they have sold, and if we got back to affordability and selling more at a lower price, we would not have this tug-of-war between insurers and manufacturers, and we would not have poor consumers in the middle, but it gets back to price.

The CHAIRMAN. Thank you.

Dr. Dusetzina, I want to get back to the price issue with you and the role that our patent system plays.

The National Academy's report highlighted anti-competitive tactics that extend patent protections for approved drugs. The Hatch-Waxman landmark law provided a pathway for the approval of generic small-molecule products, and today, generics account for 90 percent of prescriptions of that area, but uptake of biosimilar drugs has been much slower, with patent litigation and settlement agreements blocking market entry for many FDA-approved biosimilar products, so that is what I want to focus on.

This, we had a hearing on it. We looked at Humira, what happened with that drug. This week, Senator Kaine and I introduced a bipartisan bill, the Biologic Patent Transparency Act, and what it does is require the makers of biologics to publicly disclose all the patents that protect their products.

The idea there is it would give the prospective biosimilar manufacturer the information they need to know what they are getting into and also to challenge weak or invalid patents earlier in the process.

Perhaps a more important provision would prevent or deter the brand-name companies from filing patents late in the process with the sole intent of delaying market entry, and that is what has happened, it appears, with Humira.

Tell us what you think of that idea. Do you think that if we had changes in our patent law that it would help get the market—the products to market sooner without discouraging the innovation that we all want to pursue, for drug companies to pursue and manufacturer drugs that are really going to make a difference?

Dr. DUSETZINA. That is a great question, and I appreciate that.

For biosimilars, they are just going to be more expensive to develop than small-molecule drugs. The approval pathway is more complex, so it is just more expensive to get those drugs onto the market.

That means that they have not quite as large of a price reduction as we would typically expect with traditional generics, so that is why I think we are seeing slower uptake and less formulary coverage for biosimilars than what we would hope.

I think any steps that you take that would make the path to developing those products easier, clearer, less risky will probably help to make that pathway smoother for those companies and potentially could lower their prices ultimately.

The CHAIRMAN. Thank you very much.

Senator CASEY. I just have one question for Ms. Gill. I have been thinking about your testimony and the work that you had done on the Medicare Path Finder Tool.

We know now that CMS has recently announced they are making some improvements. If you were designing or itemizing recommendations this Committee could make to CMS as they consider those improvements, what would you recommend or suggest to us?

Ms. GILL. Well, I appreciate that question. Thank you.

I would say based on our investigation, just being able to see what is a preferred pharmacy in your area would be really helpful to a consumer.

The other thing that we saw from the investigation is that being able to compare more than two pharmacies at a time would also be extremely helpful.

Perhaps even looking at different ZIP codes. Many people do not just shop in the area in which they live. There can be quite dense ZIP codes.

At the same time, being able to very clearly show how well the drug is covered and not simply by things like tier 1, tier 2, or a preferred generic versus generic. These things have no real meaning to a consumer. You really need to see the total price and highlighting what that is.

In my testimony packet, just by looking up a single pharmacy, a single plan generates over nine pages of documentation trying to really untangle how difficult, almost really, honestly almost impossible it is to try and pick a plan.

I would love to mention, you know, we ask seniors to do this every year because the plans change so often.

Senator CASEY. That is very helpful. Thanks very much.

Thank you, Madam Chair.

The CHAIRMAN. Anyone else want to comment on that excellent question?

Ms. BABBRAH. I would just add—and, again, I know you are focused on the dashboard for Medicare, but there is the problem that we are facing with on the real-time pharmacy benefit check is, at least on the commercial payers, the patient out-of-pocket cost is not standardized, and so that is one thing I think that you would want to make sure, depending on which plan you are looking at, the standard—that you standardize the patient out-of-pocket cost information.

Also I want to point out the specialty meds. Again, I am not quite sure exactly how that is covered with Medicare, but if it is covered under the medical benefit, you want to make sure that that information is available as well.

Senator CASEY. Thanks.

The CHAIRMAN. Anybody else?

[No response.]

The CHAIRMAN. Thank you very much.

I want to thank all of our witnesses today. This has been extraordinarily helpful as we tackle this very vexing and important problem.

This is the second of our three hearings this round. We have done a lot of work in this area in previous Congresses, but your expertise is invaluable. You have given us a lot to think about, about

how to empower consumers to access the best prices for their medications, and ideas on how to fix what is clearly a broken system of misaligned incentives that encourage higher pharmaceutical prices.

One of the issues that makes this so difficult is when I heard the testimony yesterday, one of the witnesses who said that she has gone $10,000 in debt to afford her prescription drugs and she is on the Medicare program. She is a retiree. She has good insurance. She has a supplement, yet she is $10,000 in debt. I just think that is wrong, and it is interfering with the quality of her life in the years that, as she points out, she has left.

My first thought was why is there not a cap on the out-of-pocket cost in the Medicare prescription Part D program, and I was surprised that there was not. When you get to the catastrophic level, obviously the Federal Government is paying a far greater percentage, but there is no dollar cap, at least that I can find. That was a real surprise to me when I heard her testimony.

First, I thought, well, we should put in a cap, and perhaps, indeed, we should. Then I started thinking about it, and even if a cap is a good idea because it helps consumers, it does not address price. All it does is shift who is paying, at least that is my initial analysis, so I think that is an example of just how difficult untangling the web is for these prescription prices.

Our next hearing on the topic is going to be a deeper dive into the efforts of the administration to tackle this problem, and I commend the administration for focusing on it, for coming up with a proposed rule, for looking at the rebate issue, and we are very eager to hear from the administration.

I am very disappointed that Dr. Gottlieb from the FDA is leaving because I believe he is very committed on this issue, and he has implemented the law to try to expedite the approvals of generics and has done so with great passion. He was supposed to be one of our witnesses. Unfortunately, he will be gone by then.

I am hopeful that we can keep looking at all the steps, small and large, that we might be able to take, and that there will be—and I think you heard it today—a bipartisan consensus that this issue must be tackled, and that we can at least take some initial steps that will make a difference. To me, it is a good sign that the patent bill that I introduced this week has bipartisan support from Senator Kane, Senator Portman, Senator Shaheen, Senator Braun, and Senator Stabenow, and I am very glad to join with Senator Casey on his dashboard bill as well and increasing transparency.

I would ask that you keep your ideas coming forward to us because I think this hearing is very helpful and helps to educate people on the challenges that we face, and I am grateful for Consumer Reports doing the kind of analysis because let us be realistic. The average consumer just sees this bewildering array of plans. When you look at the ACA plans and try to figure out which one you are better off in or—and then you have got the pharmacy issue on top of that.

I agree with Ms. Gill when she said that these terms "preferred generic," "preferred pharmacy" really do not mean a lot. We need clear pricing data that is not so hard to access, and I am pleased that the State of Maine is helping to lead the way in that area.

Senator Casey, any closing thoughts from you?

Senator CASEY. Just briefly. Thank you, Chairman Collins, because we have had 2 days now of a more intensive focus on this issue, both from the perspective of individuals impacted, unfortunately adversely, adversely impacted, and today, we are able to get to a good discussion of a lot of solutions, so we are grateful that there is no shortage of ideas out there. We obviously have more work to do.

I am grateful for your willingness to not only lead on this, but to have these hearings.

One of the things that I think this hearing further affirms is the value of in-person counseling programs like the Medicare State Health Insurance Assistance Programs, or so-called "SHIPs." In Pennsylvania, we have a different acronym by the name of APPRISE to help folks navigate some of these issues.

We cannot be expected to navigate this complex web of Medicare coverage and prescription drug prices without help, and we all need help to understand this challenge.

I am pleased that we have put forward today and will continue to put forward in a bipartisan fashion, common-sense, thoughtful policy solutions that will help bring down the cost of medications, and we have to followup the hearings with actual solutions by way of taking action.

I think, Chairman Collins, you are right. This is a bipartisan concern, and I think it is a concern that people in both parties, both houses, are realizing they ignore at their peril. That is motivating the focus, and we hope will motivate the solutions and ultimately the actions.

Thanks very much.

The CHAIRMAN. Thank you.

Committee members will have until Friday, March 15th, to submit additional questions for the record, so there may be some coming your way.

Again, I want to thank each and every one of you for your work in this area and your participation in this hearing. Together, I truly believe we can come up with some solutions that will make a real difference to the patients we heard from yesterday who are representing literally millions of Americans who are struggling with the unaffordable cost of prescription drugs at the expense of their health.

Thank you, and this concludes the hearing.

[Whereupon, at 11:31 a.m., the Committee was adjourned.]

APPENDIX

Prepared Witness Statements

STATEMENT OF LISA GILL
DEPUTY EDITOR, SPECIAL PROJECTS
CONSUMER REPORTS

BEFORE THE

U.S. SENATE SPECIAL COMMITTEE ON AGING

ON
The Complex Web of Prescription Drug Prices, Part II:
Untangling the Web and Paths Forward

March 7, 2019

Chairman Collins, Ranking Member Casey, Subcommittee Members, thank you for the opportunity to be here today to discuss the findings of our special investigation on the costs of drugs for seniors covered by Medicare Part D plans.

I speak to you today as a journalist who has had the honor of working for a decade on behalf of consumers at Consumer Reports. My work has focused on healthcare and prescription and over-the-counter medications, and specifically looking at the area of consumer drug costs.

Consumer Reports is an independent, nonprofit membership organization that works to create a fairer, safer, and healthier world. For 80 years, Consumer Reports has provided evidence-based product testing and ratings, rigorous research, hard-hitting investigative journalism, public education, and steadfast policy action on behalf of consumers' interests.

We do not accept advertising. Unconstrained by commercial influences, Consumer Reports has exposed landmark public health and safety issues and strives to be a catalyst for pro-consumer changes in the marketplace.

That's why, last summer when we noticed a small study from researchers at Yale School of Medicine[1] that suggested some drugs for consumers might be less expensive if a person didn't use their Medicare Part D coverage, we decided to take a closer

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[1] Patrick Liu, BA; Sanket S. Dhruva, MD, MHS; Nilay D. Shah, PhD; Joseph S. Ross, MD, MHS. "Medicare Beneficiary Out-of-Pocket Costs for Cardiovascular Medications Available Through $4 Discount Generic Drug Programs." Annals of Int. Medicine *Letters*. July 2018.

look. Our article was published in the January 2019 issue of Consumer Reports magazine.

With the help of Consumer Reports statisticians, we designed a secret shopper test to see what we would discover about Medicare Part D pricing and in doing so, help consumers make smarter decisions with their part D plans.

Consumer Reports often uses a "secret shopper" approach to gathering retail prices of prescription and over-the-counter medications.

So we gathered a list of five, common generic medications: the cholesterol-lowering drug atorvastatin (Lipitor), the painkiller celecoxib (Celebrex), the antidepressant duloxetine (Cymbalta), the diabetes drug pioglitazone (Actos), and the blood thinner clopidogrel (Plavix).

Again with the help of CR's statisticians, we selected six, mid-sized cities across the U.S. to run our test: Seattle, Denver, Des Moines, Dallas, Pittsburgh, and Raleigh.

We chose a ZIP code in each that was near the city's center.

We wanted to replicate what a consumer would experience when signing up in 2019 for Medicare Part D plan using the five sample drugs.

Using the Medicare Plan Finder Tool, located at Medicare.gov, in each ZIP code, we selected the three plans that the tool identified as having the least expensive retail drug costs for the year.

Then, we compared what a consumer would pay with the the three low-cost plans at two different pharmacies in that ZIP code.

We did not expect to find what we did. Originally, our focus was to test the idea that certain medications might be less expensive if you skipped using your Part D coverage.

Instead, we found that what a consumer could pay for their medications could vary by hundreds of dollars, depending on a number of factors, such as which pharmacy you chose. And worse, even small mistakes during the sign-up process could cost a consumer a tremendous amount of money.

Here are several examples of the price differences we found that were highlighted in our investigation,[2]:

1. If you accidentally forgot to enter one of your drugs into the Plan Finder tool, it could be costly. In Des Moines, the annual drug cost came to **$407** through a plan called Cigna-HealthSpring Rx Secure-Essential. When a fifth drug was added, the cost jumped to **$2,948** with the same plan. The drug we left off, generic Celebrex (celecoxib), is not on the formulary of

[2] "Want to Save Hundreds of Dollars Each Year? Choose the Right Medicare Part D Plan," Nov 2018. Available at: https://www.consumerreports.org/drug-prices/medicare-part-d-drug-plan-save-hundreds-of-dollars-each-year-on-drugs/

covered drugs for that plan, so the plan would charge a person $212 each month for that medication.

In preparation for today's hearing, I looked up the retail price of generic Celebrex on GoodRx.com, a discount coupon website we often recommend people try if their drug is not well covered by their insurance plan. I personally found this drug for as little as $16 for a one month's supply at Costco and $6 at Kroger.

2. If a person just picked a pharmacy that is "convenient" they could spend a lot more money, even with the same plan. In Denver, the total cost of our five drugs at independent Cherry Creek Pharmacy was $688 through a SilverScript plan. About four miles away, at a Walgreens, the same five drugs with the same plan cost $1,687, or $999 more.

3. **If a person selected a plan simply based on the deductible amount, they could overlook much cheaper plans.** In Dallas, for example, one plan with a low $100 deductible had the highest total annual costs of the plans we analyzed, at $1,592. But another plan in the area with a $415 deductible had a total annual cost of just $574.

Our results helped us formulate consumer tips when signing up for a Part D plan. But at the heart of these tips were three specific consumer problems:

1. **It's difficult to untangle how well a drug is covered by a Part D plan**. I've included the PDFs we downloaded when we ran

the Part D plans in Denver[3] [4] [5] so you can see what the consumer experience is like. In industry lingo, classifications such as "Generic" and "Preferred Generic" have real meanings, but to a consumer ensnared in this process, it means very little.

2. **Having "Preferred Pharmacies" in each zip code could mean huge price differences for the same plan at different pharmacies.** And, it was extremely difficult for us to discern exactly which pharmacies a plan considered "preferred" – in fact, on the plan comparison pages, [see the Denver results as an example] when a pharmacy is listed, there is no indicator – only a lower price. There is an indicator at the early-stages of the comparison process, but you quickly lose that once you begin to reconfigure the data in order to make more detailed comparisons.

3. **Having "Preferred Pharmacies" could also mean a person's favorite local pharmacy charges different amounts for the same drugs with different Part D plans.** That's also what we found in Denver. Someone filling prescriptions for the five drugs we looked at, plus paying a $16 monthly premium, could pay as little as $524 for a full year. But another person—at the same store with the same prescriptions but with a different plan—would pay $1,686. Experts we talked with suggested that if a person had a favorite pharmacy, that consumers should ask the pharmacy which plans do they offer preferred pricing.

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[3] Medicare_Denver_Plan_Comparison.pdf
[4] Monthly Cost Chart_Denver_Cherry_Creek.pdf
[5] Monthly Cost Chart_Denver_Walgreens_2019

Besides the issues of consumer confusion when signing up for a Medicare Part D plan, and spending unnecessary money for prescription medication, we know from earlier nationally representative telephone surveys that older Americans are more at risk because they simply take more medications:

A 2016 Consumer Reports survey found that three-quarters of Americans 65 and older take an average of six prescription drugs.[6]

And, we learned that one-third of people 65 and older experienced drug cost hikes in the previous 12 months and paid an average of $53 more for at least one of their drugs—though others may have increased as well.

More broadly speaking, we know that when Americans face higher drug costs, even just a few dollars at the pharmacy counter can mean changes to their household spending.

In 2018, in another CR nationally representative survey of 1,180 adults who currently take a medication,[7] we found that when a person experienced an increase in the price of their medication, a third said they spent less on groceries in order to afford their medications; a third used their credit cards more often; 20 percent postponed paying other bills.

Twelve percent said they delayed retirement.

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[6] "Medicare Patients Struggle with Prescription Drug Prices," Consumer Reports, June 21, 2016. Available at: https://www.consumerreports.org/drugs/medicare-patients-struggle-with-prescription-prices/

[7] "How to Pay Less for Your Meds," Consumer Reports, Apri 5, 2018. Available at: https://www.consumerreports.org/drug-prices/how-to-pay-less-for-your-meds/

It is clear from CR research and surveys how important it is for consumers to have clear, comparative, easy-to-understand information, and we are pleased the committee is looking at this issue.

Thank you again for the opportunity to testify on this important issue for consumers.

Testimony of

Pooja Babbrah
Senior Consultant
Point-of-Care Partners, LLC

For

Special Committee on Aging
United States Senate

March 7, 2019

Mrs. Chairman, Ranking Member Casey and members of the Special Committee, thank you for inviting me to testify before your committee. My name is Pooja Babbrah. For over two decades, I have had the pleasure of working in the healthcare technology industry, primarily in the areas of electronic prescribing (ePrescribing) and eMedication Management. I started my career working for a pharmacy benefit management (PBM) company and was involved in the very early days of ePrescribing when it was first introduced to the market in the late 1990s. We have certainly come a long way since then with availability of computerized tools and information available at the point of prescribing to help physicians choose the most effective, appropriate and cost-effective therapy for their patients. I'm currently a senior consultant for Point-of-Care Partners, the leading management consultancy in ePrescribing, ePrior Authorization and formulary management. We assist a wide range of healthcare organizations to develop and implement winning health information management strategies and manage integral programs, all of which are evolving in a rapidly changing technology-driven world.

Point-of-Care Partners has been involved with real-time pharmacy benefit check (RTPBC) since early 2014. We appreciate the opportunity to provide background and insights into the current tools, standards and technology being used in the industry to bring real-time pharmacy benefit information to physicians and to address the need for this information to be accessible directly to patients to help them navigate the prescription drug landscape.

Value of Real-Time Pharmacy Benefit Check for Prescribers and Patients

We are here today to talk about price transparency and, while RTPBC can provide prescription drug out-of-pocket costs to providers, pharmacists and patients, it's important for Committee members to understand its value beyond that. RTPBC is a transaction standard being developed by the National Council for Prescription Drug Programs (NCPDP), the preeminent American National Standards Institute

(ANSI)-accredited standards development organization (SDO) for prescription transactions in the ambulatory, long-term care and post-acute care settings. RTPBC will not only show patient out-of-pocket costs, it will also give prescribers and patients cost effective alternatives to the prescribed medication along with insights into requirements by the insurance company including any prior authorization (approval by the payer), quantity limits (parameters on the number of pills a patient can get) or step therapy requirements (where a payer wants a patient to try other medications prior to the one that was prescribed). Using RTPBC, the prescriber or patient may also be alerted to the least expensive place to fill a prescription. The goal is to provide more accurate information about a patient's prescription coverage and the cost of their medications at the point of prescribing, to help avoid sticker shock at the pharmacy counter and potentially delays in starting or continuing a patient's treatment.

Studies have shown that cost is the number one reason for prescription abandonment (provider prescribes but patient does not fill the prescription) and non-adherence (patient fills the prescription and then takes a partial dose to extend the amount of medication because it is so expensive to refill). By providing insight into the cost of medications to the prescriber, we believe that RTPBC will enable prescribers to ensure that the prescriptions that get written are actually filled, and that patients take them as prescribed – greatly improving public health.

There are a few shortfalls with RTPBC as it is being deployed today, including the lack of information about potential cost-savings, discount programs and other financial support programs. It is also important to note that RTPBC is limited today to only those transactions covered by the pharmacy benefit. Some specialty medications are covered under the medical benefit, and pricing for those medications are not available with the current RTPBC transaction. Use of the RTPBC is limited in scope between PBMs and prescribers through their EHRs. We believe that it is important to expand the reach of RTPBC to additional stakeholders including the patient and patient's caregiver. Finally we believe that RTPBC should be expanded to also incorporate additional information related to the patient out-of-pocket cost for the drug. Specifically, patients and patient caregivers should have information that will help them determine whether they should obtain a prescribed medication under their prescription benefit or by paying the cash price. All stakeholders should also have access to pricing information for the pharmacies in their network that highlights where they can access the lowest negotiated price under insurance coverage or lowest cash price.

Tremendous progress has been made with the development and utilization of RTPBC. To date, the business cases for RTPBC have been driven primarily by the benefits to payers/PBMs and providers. We are confident that widespread use of RTPBC will yield a public health gain while at the same time enabling patients to receive their medications at the lowest possible cost.

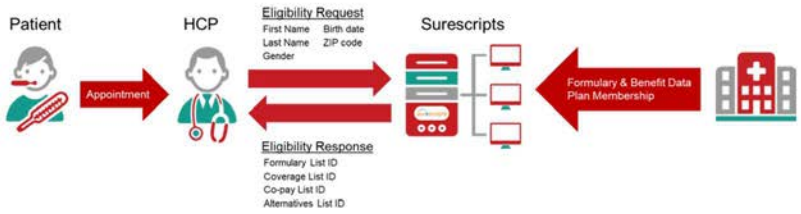
History of Real-Time Pharmacy Benefit Check

To give the committee a comprehensive overview of RTPBC, I believe it would be instructional to start with some history. The Office of the National Coordinator (ONC) for Health IT's Notice of Proposed Rule Making (NPRM) released in February 2014 was the catalyst for industry efforts around RTPBC. At the time, ONC was soliciting comments to ask a fundamental question, "Why can't the same information that is being presented at the pharmacy point-of-sale (POS) -- the term the industry uses for the pharmacy -- be presented at the point-of-care (POC)?"

This request was made by ONC in response to prescriber-identified challenges with formulary and benefit (F&B) information being presented in electronic health records (EHRs) today. Since the 1990s, health plans and PBMs have been providing formulary and benefit information on drugs covered under the pharmacy benefit to prescribers. Since the turn of the century, EHRs have used the NCPDP F&B standard, a flat file that has certain defined elements and a comprehensive set of structured data element fields.

F&B was created at a time when doctors had neither high-speed internet in their offices (to tap into the real-time information being presented at the POS) nor incentives to prescribe electronically. Physicians believed at the time that prescribing electronically would be slower than writing paper prescriptions, so F&B was created in a manner that wouldn't slow the prescriber.

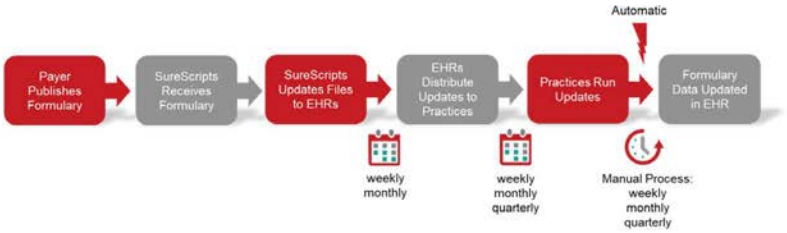
The process of leveraging F&B begins with an eligibility check that is run from the EHR, the response to which contains the identifiers to link the patient to the appropriate formulary that is provided in a separate transaction. (We in the industry call this "eligibility-informed formulary.") This information is, then, presented to the prescriber.



The source of this formulary and benefit information is pharmacy claims, dispensed prescription data and the pharmacy benefit management's benefit rules engine.

On the claims side, today pharmacy benefit management (PBM) companies extract formulary information from their claims systems, aggregate this data, add benefit information and rules, put it into the F&B standard and provide it to the largest ePrescribing intermediary, Surescripts. Several of the retail pharmacies also provide feeds of dispensed medications to Surescripts. Surescripts does quality control to the degree it can, aggregates this data and provides it electronically to their contracted EHR and ePrescribing vendors, of which there are nearly 700 such applications certified by Surescripts to display portions of this information to prescribers.[1] In 2017, Surescripts delivered more than 1.74 billion ePrescriptions, and its network included a provider directory of 1.47 million and a master patient index of 233 million patient.[2]

[1] Surescripts Certified e-Prescribing and EHR Software for Providers, accessed March 4, 2019 at https://surescripts.com/network-alliance/eprescribing-prescriber-software/.
[2] Surescripts 2017 National Progress Report.



The F&B standard was tested in the 2006 ePrescribing pilots and recommended by pilot testers in a 2007 report to Congress.[3,4] Medicare Advantage and PDP plans were mandated to use this and other standards by April 2009.[5]

While F&B is a key standard for the industry which is continually being improved, it also has its shortcomings.

Shortcomings of Formulary and Benefit

Perhaps the largest shortcoming stems from the flat file-aggregation process. Because of it, the information being presented to the prescriber is a "snapshot in time," meaning it was likely accurate as of the day the flat file was created but may not be so at the time of prescribing. You see, PBMs have Pharmacy and Therapeutics (P&T) committees that meet regularly to review literature and data and make determinations as to what drugs will be included in the formulary and any restrictions on the therapy. The P&T committee may have met – and changes been made – literally hours after the flat file was created. These updates would not be available to a prescriber until the next file has been created, processed and downloaded into the prescriber's EHR which can take, at a minimum, 14 days.

Second, because of the flat file process, the information must be presented at the plan or group level, not the individual patient level. How do we differentiate between plan-, group- and patient-level and why doges that matter? The best way to explain is in this manner: General Motors would be considered the "plan" to the insurance company, General Motors hourly employees in Bowling Green, Kentucky could be a "group" and Jane Smith would be an individual patient. Formulary and benefit information could vary by each level. For example, at the plan-level, certain drugs might not be covered but would be for hourly employees (negotiated by unions), creating discrepancies between the plan- and group-level. At the patient-level, Jane Smith could have burned through her deductible on a high-deductible health savings plan, and not be required to make co-payments at all.

Because of both F&B's flat file "snapshot in time" and "plan-group-patient level" situations, it is very difficult to give providers – to whom this is presented today – the patient's out-of-pocket cost information because there are many unknown factors such as pharmacy (in-network or out), site of service, etc. The best that insurance companies have been able to do is provide co-payment information

[3] https://www.cms.gov/Medicare/E-Health/Eprescribing/index.html .
[4] https://healthit.ahrq.gov/sites/default/files/docs/page/eRxReport.pdf.
[5] 42 CFR Part 423 published in the Federal Register April 7, 2008.

at the plan- or group-level, an incomplete picture that can cause confusion and frustration at the pharmacy or infusion center, if the cost differs from what the patient has been told.

Further complicating matters is that the comprehensive set of F&B fields are often optional, meaning that the payer doesn't have to provide all the information. This is logical because payers may not have certain pieces of information. However, some payers choose to not provide some data elements, as well. For example, while we know that Medicare requires prior authorization (PA) flags (so we know it's possible), one study using EHR formulary data for 100,000 patients revealed that only 33% of formularies contained at least one drug with a PA flag.[6] Without the flag, the prescriber does not know that PA is required so does not take steps to prospectively process an electronic prior authorization request.

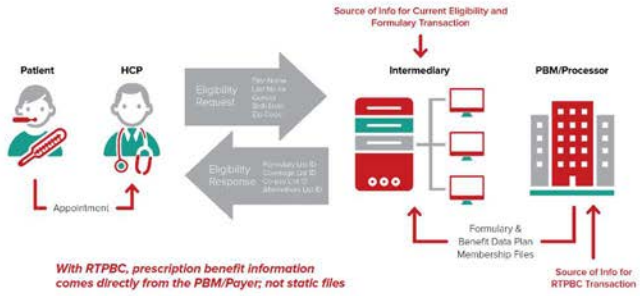
Finally, as previously mentioned, EHRs may lag in updating these files, so prescribers may not have the latest or most accurate information. Even if the file that was transmitted to Surescripts, aggregated and provided to the EHRs, at best, providers would only have access to the latest P&T committee findings.

It is these gaps that led to the creation of real-time pharmacy benefit check.

Benefits of RTPBC

In a nutshell, RTPBC delivers more accurate patient-level information about coverage and costs of drugs at the point of prescribing, to help doctors get their patients on therapy faster. Prescribers receive member price information (eg, member co-pay and cost sharing details), lower-cost therapeutic alternatives, coverage restrictions such as PA step therapy or quantity limits, channel options or the most cost-effective way for the patient to fill their prescription (ie, retail pharmacy, mail-order pharmacy, specialty pharmacy) and additional coverage and patient safety alerts.

The ability to access accurate coverage and drug cost information supports informed discussions between the prescriber and patient. This should lead to enhanced compliance with medication regimens, less prescription abandonment and fewer unnecessary office appointments, emergency department visits and hospitalizations. Prescribing the right drug for the right patient at the right time also leads to better health outcomes and improved medication adherence.



[6] AMA data presented at HIMSS19.

There is also value of RTPBC to payers. Last year, Point-of-Care Partners conducted research with executives of payers representing 95% of commercially covered lives, finding that these payers view RTPBC as a way to improve their basic, core performance indicators including drug utilization and costs; and administrative costs,[7] such as prior authorization.

Adoption of RTPBC

Since 2015, several vendors have developed RTPBC services. According to the most recent industry reports, 73% of the current EHR market, and 81% of the payer market, representing the majority of market share, have at least one of these RTPBC solutions integrated into their system.[8] Provider adoption of these services is also growing. According to the most recent report from Surescripts, as of December 2018, more than 100,000 prescribers are using their solution which translated into 6,300,000 transactions in the month of December.[9]

Finally, according to a recent report by CVS Health, prescribers using CVS Health's real-time benefits information are, on average, saving their patients $120-$130 per prescription by switching to a covered drug. According to the report, prescribers are switching to a covered drug 75% of the time, when the originally prescribed drug is not on the member's formulary. In situations where the original drug is covered, but a lower cost alternative is available, prescribers are switching patients to a clinically appropriate alternative 40% of the time, resulting in average out-of-pocket member savings of $130 per filled prescription.[10] Despite significant progress in adoption and impact, the industry still has a long way to go before we can realize the full potential of this transaction.

Shortfalls in Real-Time Pharmacy Benefit Check

The information currently provided in the RTPBC response from the PBM or payer to the physician has some inherent shortfalls. Today, the patient out-of-pocket cost data that is sent back to the physician only reflects the amount the patient will pay ***if*** they use their insurance coverage. In some cases, using insurance may not be the most cost-effective method for the patient. This is especially true for those who may have a high-deductible plan who have not yet met their annual deductible or for drugs that are offered by certain pharmacies at a lower cost than co-pay. In other situations, the drug may be covered under the patients' medical benefit as opposed to their pharmacy benefit. This is often the case for many of the high cost specialty medications. If a prescriber runs an RTPBC for a specialty medication, the prescriber may receive a message that the drug is not covered since RTPBC only checks the prescription coverage for a medication, not the medical benefit coverage.

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[7] "Real-Time Pharmacy Benefit: The Payer Value Proposition", Point-of-Care-Partners, November 2018.

[8] https://www.covermymeds.com/main/insights/rtbc-scorecard/; accessed March 2018.

[9] https://surescripts.com/docs/default-source/intelligence-in-action/prescription-accuracy/2_2019-price-transparency-impact-report-data-brief.pdf; accessed March 2018.

[10] https://payorsolutions.cvshealth.com/insights/proven-savings-with-real-time-prescription-benefits; accessed March, 2018.

Second, one of the key aspects of RTPBC is the ability to provide an accurate out-of-pocket cost to the member. Unfortunately, the calculation of this amount is currently not consistent across each payer and PBM. In some cases, the PBM presents "patient pay amount" but does not always include deductible. In other cases, the patient out-of-pocket cost may be different for prescriptions filled with an in-network pharmacy vs. one out-of-network. If this information is not calculated into the response, what is displayed to the prescriber may not be accurate. Inaccuracies resulting from incomplete inputs could lead to similar frustration as the use of F&B files have caused. Patients want to be confident the out-of-pocket amount discussed with their doctor is what they can expect when they arrive at the pharmacy to fill their prescription.

Manufacturer discount programs such as patient co-pay assistance, manufacturer coupons or additional information around potential financial assistance through foundations and other organizations are other important payment factors. There has been industry discussion about whether access to these financial assistance programs may have unintended consequences. PBMs and payers believe these options may lead patients to start on a more expensive but less or equally efficacious medication. While drug manufacturers and other stakeholders continue to provide these options, which may be part of marketing efforts, but they do help lower the out of pocket cost of the medication for the patient. This "tug-of-war" between the PBMs and Manufacturers will likely continue.

Finally, there are several companies providing prescription discount cards and services for patients who pay cash for their prescriptions, but these services are, for the most part, available outside of the prescribing workflow and normally not accessed by the patient at the pharmacy counter after the prescription has been sent to the pharmacy.

Opportunities to Improve the Availability of Real-Time Pharmacy Benefit Check

Access to the RTPBC transaction is limited primarily to a prescriber's EHR. Today, for the most part, RTPBC is a transaction between a prescriber using their EHR and the PBM or payer. Some pharmacies and pharmacy systems are accessing this transaction with the payer, but there is little to no availability of RTPBC information direct to the patient. Some opportunities for improvement include:

Pharmacist Access to Real-Time Pharmacy Benefit Check. In October 2018, President Trump signed the "Know the Lowest Price Act" and the "Patients' Right to Know Drug Prices Act" into law, which removed the "gag clause" preventing pharmacists from consulting patients on lower cost medications. Although pharmacists can now have these consultations, most pharmacists do not have the tools to do so. Today, the transaction that informs the pharmacists in the pharmacy system is the NCPDP Telecommunications Standard. This standard is primarily used to adjudicate a pharmacy claim. This standard allows a pharmacist to determine if a medication is covered by the patient's prescription coverage; however, it does not return additional information on lower cost alternatives or a cash price for the patient. Implementation of RTPBC in pharmacy systems would allow pharmacists to have the tools needed to inform the patients of their options and help them navigate the prescription drug landscape.

Patient Access to Real-Time Pharmacy Benefit Check. Patients will also benefit from access to RTPBC data. While availability of RTPBC data directly to patients is limited, some PBMs and payers are giving patients access to this information through their portals. RTPBC data provided by PBMs usually does not

include availability of cost savings and/or cost reduction coupons or the cash price. Portals are not necessarily the most convenient way for patients to access the information that is available; an app a patient can open while at the pharmacy counter is a more likely scenario and more convenient for the patient. In order to improve the type of data available and methods of access to patients, Point-of-Care Partners recently began working with the CARIN alliance to develop a patient-facing RTPBC transaction.

As background, the CARIN Alliance[11] is a non-partisan, multi-sector alliance co-founded by former National Coordinators for Health IT, Dr. David Blumenthal and Dr. David Brailer; former White House Chief Technology Officer, Aneesh Chopra; and former Utah Governor and Secretary of Health and Human Services, the Honorable Michael Leavitt. The Alliance comprises stakeholders representing all areas of the health care delivery system including government, providers, payers, health systems, consumers, patient and caregiver advocates, electronic health record providers, consumer platform companies, and third-party consumer application solutions. The CARIN Alliance's vision is to advance the ability for consumers and their authorized caregivers to easily get, use, and share their digital health information when, where, and how they want to achieve their goals.

As it relates to a patient-facing version of RTPBC, the alliance is working with Point of Care partners to develop a new pathway to allow patients direct access to their prescription drug information via an application programming interface or API to a third-party application of their choice to help them navigate the prescription drug landscape. The alliance has recently put together a Real-Time Pharmacy Benefit Check Work Group and is convening multiple stakeholders, such as payers, patient groups, and provider groups and additional health sector representatives such as manufacturers, PBMs, and pharmacies to help operationalize the "Know the Lowest Price Act" and the "Patients' Right to Know Drug Prices Act" by empowering consumers with both the real-time pharmacy benefit check and cash price information they need to make a more informed decision regarding the price of their prescription drugs. It's anticipated that once developed, many of these providers, payers, application companies, and others will voluntarily implement the new patient-facing real-time pharmacy benefit check capability thus helping millions of consumers to access more timely and accurate formulary and cash price information for themselves and their families.

Policy Considerations for RTPBC

Point-of-Care Partners supports public policy change as it relates to RTPBC to ensure completeness and accuracy of the information provided by the PBM or payer and the broad availability of the transaction to all stakeholders. The Notice of Proposed Rule Making released by CMS in November 2018 titled "Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses," (CMS-4180-P) could lead to the adoption of Real-Time Pharmacy Benefit Check beginning as early as January 1, 2020. The adoption by Medicare Part D will hasten adoption by other stakeholders. Point-of-Care Partners provided comments on the proposal,[12] some of which I will summarize now along with additional policy recommendations that should be considered by the committee.

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[11] For more information including a list of organizations currently participating in the CARIN Alliance, please visit www.carinalliance.com.

[12] https://www.pocp.com/wp-content/uploads/POCP_Comments_PartD-NPRM-re-RTPBC_December-2018.pdf.

As it relates to the CMS NPRM, we have provided the following commentary:

1. **Name of the transaction.** The proposed rule references a Real-Time Benefit Tool (RTBT). We believe the term "tool" is a misnomer. To some, it refers to proprietary implementations currently in the market, and could be misinterpreted as a piece of software. What is being developed is a transaction specification, which will be adopted by industry stakeholders. The transaction in question is one in the ePrescribing process that is referred to in the industry as a Real-Time Benefit Check (RTBC). Point-of-Care Partners believes it should be called the Real-Time Pharmacy Benefit Check (RTPBC). That is because the transaction refers to an electronic benefit check for drugs covered under the patient's pharmacy or prescription benefit. It is distinct from a similar transaction for checking benefits for drugs, devices, and procedures or drugs covered under the patient's medical benefit. The industry is beginning work on what could be called a real-time medical benefit check (RTMBC).

2. **Use of standards.** The proposed rule is agnostic in terms of a standard to be used for the RTPBC. In the past, the lack of a clearly identified, candidate standard at the time of rulemaking has created downstream challenges related to implementing and updating HIPAA standards. The draft regulation indicates that if an RTPBC standard is available in a year or so, it could be adopted by Part D for 2021. Point-of-Care Partners recommends a single standard be named because it will hasten adoption of the transaction and eliminate the potential for an unsustainable number of one-off solutions. If CMS decides to name a specific standard and version, it should do so with an eye toward syncing updates with forthcoming requirements from ONC and recommendations from the National Committee on Vital and Health Statistics (NCVHS). ONC is seeking public comment on its recently released draft Strategy on Reducing Burden Relating to the Use of Health IT and EHRs. The Strategy is designed to reduce administrative and regulatory burdens associated with the health information technology infrastructure, such as standards versioning and updates. NCVHS is concluding its work on ways to speed up the standards adoption process and will be forwarding its recommendations soon to CMS. Finally, if a specific standard is selected, CMS should require the development of a standard implementation guide to ensure consistent, industry-wide execution.

3. **Address the relationship with formulary and benefit files.** The proposed rule does not address the interaction between RTPBC and the formulary and benefit (F&B) standard. This is an important issue and needs to be clarified in the final rule. Some believe that the RTPBC will replace the need for F&B files. Others believe the need for F&B files will not go away with the adoption of RTPBC. Rather, F&B will evolve to support RTPBC by consistently alerting prescribers of the need to perform an RTPBC due to mitigating factors, such as noncovered drugs. Thus, eligibility-informed formulary is still important because it helps determine whether an RTPBC is needed. For this to work well, however, two things have to happen. First, commercial payers have to populate the prior authorization field in the F&B file and make it available in the RTPBC response, and payers must address the gaps in F&B data. As a result, we recommend that CMS require payers to provide a minimum mandatory data set to populate F&B files as well as populate the prior authorization field in F&B files. Second, the final rule should specify that the RTPBC does not replace the eligibility-informed F&B check.

4. **Establish a uniform patient out-of-pocket cost model**. Because of the way RTPBC has evolved, there are varying models for patient out-of-pocket costs. We recommend that CMS work with industry to create a uniform patient out-of-pocket cost model. This is needed to ensure that payers provide consistent and uniform out-of-pocket cost information.

5. **Integrate additional cost/access information.** Information gaps affecting patients' potential out-of-pocket liability exist today with real-time pharmacy benefit check. It begins with co-pay, which can vary by medication, patient and plan. In the proposed rule, CMS requires plans to share the negotiated price of a drug with the consumer. Point-of-Care Partners recommends that CMS require the inclusion of not only negotiated price in RTPBC, but a broader category of comparative pricing. Specifically, we believe prescribers and patients should have information that will help them determine whether they should obtain a prescribed drug under their insurance benefit or under a possibly less expensive cash price. We also believe that under either of these scenarios, individuals should have access to pricing information for the pharmacies in their network that highlights where they can access the lowest negotiated price under insurance coverage or lowest cash price.

   There is financial assistance offered by manufacturers, foundations, and states. For example, many manufacturers fund coupon and co-pay card programs to offset the costs of drugs for consumers. In fact, manufacturers offer coupons for nearly half of the top 200 drugs, creating billions of dollars in potential savings opportunities. They also fund financial assistance for patients' drug co-pays or other medical expenses through nonprofit foundations. Many states have similar programs, although details vary as to for whom and what conditions may be covered. Several payers also offer drug assistance programs. Having this kind of information in the real-time pharmacy benefit check can help the physician truly identify the most cost-effective options for their patients, ultimately improving outcomes and medication adherence and reducing costs.

6. **Enable RTPBC access for patients.** Today, patients often do not fully understand the cost of new medication therapy until they arrive at the pharmacy, and in some cases, cannot afford it. If patients had access to RTPBC, they could have full visibility into their and their family members' medication costs, alternatives, coverage restrictions, assistance programs and pharmacy options prior to arriving at the pharmacy. Once payers build RTPBC for providers, it would be feasible to allow patients to access the same data via portals or apps. Some payers currently provide patient-facing apps and portals today to allow patients to check the coverage and out-of-pocket cost of their medications, and there are patient-facing apps not affiliated with payers and PBMs to check the cash price for a medication, but there are few if any forums that have all the information in one convenient place. Patient access to cash drug price at their selected pharmacy is a required disclosure under recent "gag" clause changes. Some market-based tools even offer drug price cash comparison capabilities.

   From a policy perspective, we see several benefits of including comparative price information in real-time consumer drug price access tools. One benefit is to help ensure active compliance with gag clause requirements. Enabling patients to compare coverage prices vs. cash prices at multiple pharmacy locations will facilitate true comparison shopping and patient engagement in their health care costs.

Stakeholders may also benefit from increased information sharing about fulfillment of prescriptions through cash pay transactions. Today, there is no mechanism for plans to record or track patient medication purchases made in cash. Closing this loop will contribute to better care coordination for the patient and can help plans as they strive to meet quality measures and improved outcomes.

7. **Erasing the "gag" rule culture.** Additional legislation should be passed to make RTPBC available for pharmacists. Great progress was made with the recent passage of the Patient Right to Know Drug Prices Act and the Know the Lowest Price Act of 2018 to remove the "gag order" clauses in contracts between pharmacies and payers or PBMs. But for a pharmacist to be able to proactively inform patients of the availability of a less costly drug or that cash payment is less than co-pay, pharmacists needs tools including RTPBC. RTPBC access for prescribers, patients and pharmacists will help create a new culture of transparency and open discussion.

Point-of-Care Partners, like CMS, ONC and many other key players in the industry, see the value in increasing drug price transparency, specifically through access to real-time pharmacy benefit check for prescribers, pharmacists and patients. The time and conditions are right to provide accurate, timely and patient-specific prescription drug coverage information as an enabler for stakeholders to choose the lower priced drug option, increased adherence and eventually improved patient outcomes.

Thank you for the opportunity to testify today. I would be happy to answer your questions.

Testimony of Stacie B. Dusetzina, PhD
Associate Professor of Health Policy and Ingram Associate Professor of Cancer Research
Vanderbilt University School of Medicine, Nashville, Tennessee

HEARING TITLE: The Complex Web of Prescription Drug Prices
Part II: Untangling the Web and Paths Forward

Before the United States Senate Aging Committee
March 7th, 2019

Chairman Collins, Ranking Member Casey, and distinguished members of the Committee,

Thank you for the opportunity to testify today on the topic of prescription drug access and affordability.

My name is Stacie Dusetzina and I am an Associate Professor of Health Policy at Vanderbilt University School of Medicine. I have spent my professional career focused on prescription drugs and the policies that facilitate or impede their use. I was also a member of the National Academy of Medicine's committee on ensuring patient access to affordable drug therapies. The findings and recommendations of this consensus study report were published last year under the title "*Making Medicines Affordable: A National Imperative.*"

My research includes findings related to the prescription drug supply chain, including the role of drug rebates for increasing patient and taxpayer spending in the Medicare Part D program,[1,2] how having higher out-of-pocket costs is associated with lower use of needed medications,[3,4] and how prescription drug list prices and price increases over time have made many drugs unaffordable for Americans.[5-8] My work has touched on access to prescription drugs for patients who are Medicare beneficiaries, enrolled in commercial health insurance plans, or uninsured.

In the United States, many patients are facing the reality that prescription drugs are unaffordable for them. Patients are choosing to go without treatment, even if that puts their lives at risk. For example, our work has shown that the Medicare Part D benefit requires patients to pay a percentage of the drug's price for virtually all anticancer drugs. This means that most Medicare beneficiaries needing these drugs will spend thousands of dollars out of pocket to fill their first prescription and, in some cases, over one thousand dollars per month after they reach the catastrophic coverage of the benefit. This has also been shown to occur for patients with other complex diseases.

Commercially-insured patients are also exposed to high out-of-pocket spending in some cases; particularly when they are paying deductibles (paying full price for drugs until you hit a pre-specified level of spending like $2,500) and coinsurance (paying a percentage of the drug's price instead of a flat fee). Deductibles and coinsurance have become more common in recent years in commercial health plans and they are used in the Medicare Part D benefit, as well. Under both arrangements, patient out-of-pocket spending is calculated using the drug's "list price", which can be much higher than the price paid by the health insurance plan or the pharmacy benefits manager. For example, a patient filling an 84-day course of hepatitis C treatment on Part D

would have their out-of-pocket costs calculated based on the list price of nearly $93,000 instead of the net price paid by their insurer and PBM of roughly $35,000.[2] This could make a big difference in how much a patient is expected to spend, but both of these prices are likely to result in an out-of-pocket spending that is completely unaffordable for most people.

Insurance should be designed in a way that protects people from catastrophic levels of health care spending when they are sick. Today's Part D program does not function in that way. Instead, patients needing expensive drugs or using many drugs are exposed to unlimited out-of-pocket spending. To add to the confusion, patients cannot easily predict how much they will pay during any given visit to the pharmacy and their prices may differ at one pharmacy versus another in their same neighborhood, even under the same health plan.

Congress and the American public have heard and will continue to hear from other stakeholders involved in the prescription drug supply chain. They all point to each other as the reason for such problems. In fact, they all contribute and they all need to be engaged in solutions. The complexity of the prescription drug supply chain makes single or narrowly focused policy proposals risky. This is indeed a complex area and solutions will be complex, too.

When considering solutions, I would recommend focusing on three key goals:

1) Ensuring that patients have access to high value drugs at reasonable out-of-pocket cost.
2) Removing incentives for high list prices and price increases.
3) Encourage innovation by paying for value.

I thank the Committee for the opportunity to be here today and look forward to working with you on solutions to these complex problems.

Prescription Drug Spending in the United States

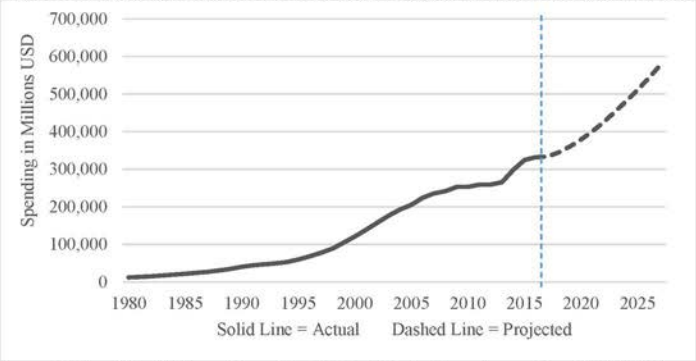
In 2017, national health expenditures for retail prescription drugs (those filled in retail pharmacies) reached nearly $334 billion and recent projections suggest that spending could reach nearly $600 billion by 2027.[9] The United States now spends more on prescription drugs than other high-income countries, largely explained by higher prices paid by insurers and consumers.[10-13] Brand named drug prices for widely used prescriptions increased by 8.4% in 2017, four times the rate of inflation.[14] The number of high priced specialty drugs has also increased over time, with spending on these drugs likely now exceeding 50% of retail prescription drug spending on commercial health plans.[15] The introduction of new and exciting technologies like curative therapies for Hepatitis C, and gene and cell therapies used to treat rare diseases such as inherited blindness and cancers for which other treatments have failed promise major advances for patients but boast substantial prices. We may in fact develop cures for diseases that only the wealthiest among us can access.

Spending on health care, including prescription drugs, is a cost that we all bear. We bear costs directly in higher premiums and less generous insurance coverage when we need to seek care. We bear costs in stagnant wages as employers aim to shield employees from rising costs. We bear costs as our taxes pay for Medicare and Medicaid.

In 2016, on average, Medicare households spent 14% of their income on health care (or $5,355 annually); nearly the same amount spent on food.[16] For those with complex health care needs, they will spend much more.

In 2015, approximately one million Medicare beneficiaries who lack out-of-pocket subsidies reached catastrophic spending levels in Part D.[17] Under the current system, as drug list prices continue to climb, we should expect to see continued growth in both patient and taxpayer spending on the Part D benefit.[1] For patients filling anticancer drugs on Part D, our work has shown that they can reach catastrophic spending with one fill (or roughly one month of drug supply).[5] Others have shown that for patients using high priced "specialty" drugs, most will spend more in the catastrophic part of the Part D benefit than in the other phases of the benefit combined.[18] This means that closing the "doughnut hole" has done little to reduce patient out-of-pocket spending on high priced drugs.

Figure 1. Projected National Health Care Spending on Retail Prescription Drugs Through 2027



Source: National Health Expenditures Historical and Projections. Accessed on 2/27/2019 from https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html

Why are drug prices so high?

Drug prices are high in many cases because, aside from public pressure, companies lack motivation to make drugs more affordable. This is particularly true for branded drugs that have limited or no competition[13] and for products where payer and pharmacy benefit manager (PBM) negotiation is not functioning due to mandatory formulary inclusion of products. Even with substantial public pressure, prices are not reduced in many cases.

Take for example the now infamous drug, Daraprim, used to treat an infection called toxoplasmosis. Turing Pharmaceuticals CEO, Martin Shkreli obtained this product and increased the price from $13.50/tablet to $750/tablet. Despite extensive criticism by the public, media, and Congress, the price remains unchanged today and a 90-tablet prescription has a price of almost $70,000.[19,20] In another example, a cancer drug maker was criticized last year by physicians regarding a new pricing strategy that created a single price across a variety of drug doses when evidence suggested that patients could use a lower dose and still obtain benefit.[21,22] The company

faced some significant media and public criticism and responded at that time that they would not increase prices as planned for the 140mg product.[23] While they kept the original 140mg version of the drug on the market, they also moved forward with the planned price increase under the new one-pill-one-price scheme where the 140mg pill has a price that is three times that of the original version. In the Medicare Part D plan finder the 140mg version of their product in a capsule costs $4,315/month while the 140mg tablet costs $12,682/month.

Companies largely set prices using a "what the market will bear" approach, often justifying very high prices by concerns related to the size of the population that could be treated, the costs of research and development, and the length of time available to recoup these investments. Notably, these factors are typically used to justify high prices but are rarely used to lower prices. Even in instances where products are introduced to the market at very high prices, year-to-year list price increases for these products are often well above inflation.[7,24,25]

Prescription Drug Coverage in the United States

Out-of-pocket spending for prescription drugs is a key concern for Americans. According to a February 2019 public opinion poll, 79% of respondents believe the costs of prescription drugs is unreasonable and a majority endorse a broad range of proposals to keep costs down.[26]

What patients pay is related to how they are insured. In 2017, over half of the population had commercial insurance (employer sponsored or individually-purchased), 21% had Medicaid insurance, 14% had Medicare insurance, and 9% were uninsured.[27] My remarks will focus on out-of-pocket spending for commercially-insured and Medicare insured individuals. However, it is important to note that patients without insurance would likely find that virtually all branded prescription drugs are unaffordable to them. In addition, these patients pay based on the drug's list price and they are typically not allowed to obtain prescription drug copayment coupons to help to lower their out-of-pocket spending. They face extensive barriers to receiving medications, highlighting the importance of insurance in this context.

Side Effects of High Drug Prices: Financial Toxicity

One of the principle concerns around excessive patient out-of-pocket spending is "financial toxicity".[28] This concept has been defined as a key issue for patients undergoing treatment for cancer but can be extended to other areas. For those patients who have substantial out-of-pocket spending, they may exhaust savings and retirement accounts, face housing insecurity, borrow money, or file for bankruptcy due to medical bills.[28] It is also well documented that higher cost sharing or unexpected changes in costs for prescription drugs can reduce patient uptake and adherence to treatments, particularly for high priced drugs.[3,4,29-32]

Patients in employer-sponsored plans are now paying more of their out-of-pocket costs for retail prescription in the form of deductibles and coinsurance, as opposed to copays. For example, out-of-pocket spending on deductibles for commercially-insured patients grew from 28.8 percent of total cost-sharing payments in 2006 to 51.7 percent in 2016.[33] Despite having out-of-pocket maximums, many people in commercial health plans would still struggle to afford their prescriptions and these limits are high – currently $7,900/individual or $15,800/family. Some of my prior work has documented that, even for patients taking life saving cancer drugs, having modestly higher out-of-pocket costs was related to patients discontinuing treatment or taking less medication than prescribed. For example, patients with monthly out-of-pocket costs above

approximately $50 had a 70% higher risk of discontinuing their cancer treatment compared with those with lower out-of-pocket costs.[3]

For Medicare beneficiaries, receiving Part D, those who do not receive low-income subsidies can face substantial out-of-pocket costs for prescriptions, particularly if they use expensive specialty drugs or multiple higher-cost brand-name drugs.[5,17,18,34] Unlike most commercial insurance plans, Medicare Part D does not include a hard, annual cap on out-of-pocket costs for prescription drugs. This is true for people in traditional "fee-for-service" Medicare plans and those in Medicare Advantage plans. Today many beneficiaries have higher out-of-pocket spending in the catastrophic phase of Part D than in the other benefit phases combined.[17,18]

For patients with commercial insurance or Medicare Part D who are paying deductibles or coinsurance, they pay these costs on the drug's list price. For patients who are uninsured, they also face the full drug list price when filling prescriptions. Our prior work has shown that health plans, PBMs, and manufacturers all benefit in Medicare Part D when list prices increase as patients and taxpayers take on more spending in these cases.[1] List price is important for patients and increases in list prices make drugs less affordable for many patients.

National Academy of Medicine Report Recommendations

In 2018, the National Academy of Medicine released a report documenting key findings and recommendations related to making medications more affordable.[35] Notably, as recommendations were made in the context of a complex and opaque system, implementation of these recommendations will likely be complex. In some cases, there may be opportunities to consider demonstration or pilot projects to study the likely impact of these actions before full implementation is pursued. Further, actions directed at one area will have spillover effects in other areas, making it important to partner efforts to lower costs to patients with other initiatives to manage drug spending more broadly.

These recommendations include the following[35]:

a. Accelerate the market entry and use of safe and effective generics as well as biosimilars, and foster competition to ensure the continued affordability and availability of these products.
b. Consolidate and apply governmental purchasing power, strengthen formulary design, and improve drug valuation methods.
c. Assure greater transparency of financial flows and profit margins in the biopharmaceutical supply chain.
d. Promote the adoption of industry codes of conduct, and discourage direct-to-consumer advertising of prescription drugs as well as direct financial incentives for patients.
e. Modify insurance benefits designs to mitigate prescription drug cost burdens for patients.
f. Eliminate misapplication of funds and inefficiencies in federal discount programs that are intended to aid vulnerable populations.
g. Ensure that financial incentives for the prevention and treatment of rare diseases are not extended to widely sold drugs.
h. Increase available information and implement reimbursement incentives to more closely align prescribing practices of clinicians with treatment value.

I believe that the Committee should prioritize actions related to the following recommendations: expediting generic entry, strengthening formulary design and improving drug valuation methods, increasing transparency, and modifying insurance benefit designs for lowering out-of-pocket spending (recommendations a, b, c, and e). These changes could produce meaningful savings for taxpayers and patients. I discuss each of these areas below.

Accelerate Generic Entry / Increase Competition

Scholars have noted the importance of generic competition for driving down drug spending by payers and patients.[13,36,37] Branded drug manufacturers typically get an average of 12-14 years of competition free exclusivity[38,39]. After this point, generic drug products can enter the market, offering lower priced options for patients and payers. Historically, generic entry and uptake has dramatically reduced spending for commonly used products such as statins and antihypertensive drugs. While the U.S. Food and Drug Administration has increased the number of generic drug approvals substantially over recent years,[40] competition is often dampened through anticompetitive tactics used by branded drug manufacturers such as "pay for delay", "product hopping", and blocking access to product samples needed for competitors to complete bioequivalence testing for FDA approval.[41] Opportunities to address many of these anticompetitive tactics that serve as barriers to generic drug entry have been highlighted within recent Congressional hearings.[42,43]

Even after products are approved, uptake of generic or biosimilar products may be hampered by health plans and PBMs electing to provide "preferred" status to branded drugs over the generic entrant. Plans would likely elect to encourage branded drugs over generics in cases where net prices for branded drugs (after rebates or discounts) are similar or lower than generic drug prices.[18] This is theoretically more likely to occur with "specialty" generic drugs and biosimilars as these products often have fewer generic manufacturer entrants than in the traditional generic drug market.[25,44] Indeed, evidence of such behavior is beginning to emerge.[18,45,46]

Notably, by covering branded drugs on preferred status over generics, this may serve to further discourage generic competition, impeding generic drug price decreases. Patients who elect to take a generic drug in these instances may find themselves paying more for it than the branded drug, an obvious concern for encouraging generic drug use. Furthermore, for Medicare Part D beneficiaries who have high levels of drug spending, those who use generic drugs could pay more out-of-pocket for these products relative to using brands due to the coverage gap discount program. This program currently requires drug manufacturers to pay 70% of the branded drug price for products filled in the coverage gap (doughnut hole). These funds are then counted as beneficiary out-of-pocket spending and they help patients to reach the catastrophic phase of coverage faster. For example, in 2019 branded drug users who enter the coverage gap would reach catastrophic coverage after spending $982 out-of-pocket versus $3,730 for generic drug users (who get no manufacturer contributions).

The Committee should consider opportunities to increase competition in the specialty generic drug and biosimilar market, including modifying the Part D benefit to remove incentives for plans to use branded drugs when generics are available.

Increase Negotiating Success
The National Academy of Medicine report noted several opportunities to improve negotiations for prescription drugs, including by consolidating purchasing power, testing methods for determining product value, and allowing more flexibility in formulary design.

Regarding consolidating negotiating under Medicare Part D, there is disagreement among experts regarding the relative value of allowing the Secretary of Health and Human Services to negotiate on behalf of the Medicare Part D program. Currently, several PBMs operate on behalf of Medicare beneficiaries today and each represent millions of covered lives in the Medicare Part D program and through their commercial clients. Further consolidation of purchasing power may not drive much deeper discounts unless stricter formulary management efforts were also available.

Efforts to improve negotiations are complex, primarily because we lack leverage for negotiating in precisely those areas where treatment options are limited, or disease are complex. Notably, due to protections built into the Part D program when it was initially developed, plans are required to cover at least two products within every drug class and all the products in the "protected classes." Protected class drugs have historically achieved very low rebates and discounts relative to drugs outside of these classes, particularly for drugs for complex diseases such as cancer, rheumatoid arthritis, and multiple sclerosis. Mandatory coverage of these products effectively reduces plan / PBM ability to negotiate, which results in higher prices to taxpayers and to patients needing such drugs.

Proposals to modify the benefit design and relax rules related to "protected class" status have been made in an attempt to reduce spending by the Part D plan sponsors and beneficiaries. However, changes to protected classes should be approached cautiously due to the importance of these drugs for patients. The Congress should carefully evaluate whether drugs within the protected classes should be subject to more scrutiny, either when prices are initially set or when prices increase.

Reference pricing, value-based pricing, or arbitration have been proposed as ways to ensure that drugs that have limited competition are priced appropriately when introduced on the market.[47] These tools could also be used to determine formulary placement of products, including which drugs should be offered at low cost or, possibly, no cost to patients.

Increasing Transparency in Financial Flows
We lack critical information regarding who benefits most under current payment arrangements. There is an intentional lack of transparency within the drug pricing and reimbursement system that should be addressed.[35] There are some concerns that disclosure of rebates or other price concessions may increase Medicare spending if the Part D program currently extracts larger rebates than other payers. This could theoretically occur as payers that received the largest discounts could see those discounts shrink as payers with the smallest discounts demanded lower prices. Further, there are risks that disclosure could lead to tacit collusion among companies offering similar products. The Congressional Budget Office reviewed the potential impact of disclosure in 2003 and 2007 but, to my knowledge, has not evaluated this topic since. In 2007, they determined that disclosure of Medicare rebate data would have a smaller upward impact on

prices than originally assumed.[48] It may be useful to revisit these estimates to understand the likely impact of transparency today as plans now have substantial experience with the Part D.

Transparency efforts have been proposed in some states or for some select products (e.g., insulin) and have been met with fierce resistance from the industry. However, limited disclosure of information to relevant parties may protect confidentiality of negotiations while creating a deeper understanding of areas in need of reform. Given the goals of each supply chain member to maximize their own profits, it may be beneficial to require transparency on the many transactions occurring in the system to better target policies for reducing spending overall. For example, understanding the net payments made by the health plan and PBM and the net price received from drug manufacturer would provide needed insight into how well our current negotiations are working to lower spending overall (versus shifting profits from drug manufacturers to other supply chain members).

Modifying Insurance Benefits to Lower Out-of-Pocket Spending for Patients

Patients need financial relief from high drug prices. Several policy options aimed at providing out-of-pocket savings for patients and potential challenges related to their implementation are noted below. Notably, these efforts to limit patient out-of-pocket spending must be coupled with efforts to limit drug spending more broadly to ensure that changes made here do not exacerbate drug spending overall.

Use copayments rather than coinsurance

Use of copayments (flat fees) for preferred drugs - rather than coinsurance and deductibles - may improve patient access and adherence to high-value treatments by providing more predictability for out-of-pocket expenses for patients. Because such a design may make patients less price sensitive (relative to paying a percentage of the drug's list price) plans could differentiate between preferred and non-preferred products through use of copayment tiers (with lower copayments for preferred products) to steer patients to more cost-effective treatments when competitors exist within a drug class. This recommendation would also require a statutory change to the standard benefit design in Part D, which currently requires coinsurance during the coverage gap, regardless of a plan's cost-sharing design in the initial coverage phase.

Align cost sharing to reflect value

For drugs that provide high value for preventing disease or managing disease progression, payers could use "value based" benefit design to increase access to certain high-value prescription drugs[49]. Drugs used to prevent chronic disease progression or complications could be exempt from deductibles or subject to preferred (or zero) cost sharing. Evidence from value-based health plan design has focused primarily on chronic disease medications with generic competitors,[50] but this approach could also be used to offer specialty drugs with very high clinical benefit at lower out-of-pocket costs to patients.

Limit out-of-pocket spending in Part D

Medicare Part D does not currently have an annual out-of-pocket spending maximum for outpatient prescription drugs. Policymakers should consider placing a limit on out-of-pocket prescription drug spending in Part D by removing the 5 percent coinsurance payment from the

catastrophic phase of benefit. For patients using expensive drugs, the 5 percent coinsurance can represent a significant financial burden.

If an out-of-pocket spending limit is placed on Part D, the benefit should also be revised to ensure that incentives that plans and manufacturers currently have for increasing list prices are removed. One proposal advanced by the Medicare Payment Advisory Committee (MedPAC) and through the administration's Drug Pricing Blueprint recommends reducing Medicare's catastrophic phase reinsurance from 80% to 20% by incrementally increasing the proportion paid by the Part D plan sponsor and eliminating patient out-of- pocket contributions.[51]

Passing Through Rebates at the Point of Sale

Rebates paid to PBMs by drug manufacturers have been intensely criticized as driving up costs to individual patients who do not benefit directly from rebates at the point-of-sale. The administration recently proposed to effectively eliminate rebates from Medicare Part D, except in cases where they were fully passed through to the patient at the point of sale. Rebates can be large for some products where competition is robust. Insulin and Hepatitis C are two examples of products with large rebates, with an estimated 60% difference between list prices and net prices.[2] Rebates for non-competitive drugs or those in protected classes, on the other hand, are known to be limited. For example, estimated rebates for anticancer drugs are less than 12%.[2] Even if manufacturers converted their rebates to upfront discounts, only those taking drugs in competitive classes would realize savings; patients taking some of the most expensive medications would not. Furthermore, drug manufacturers are not likely to lower their list prices by as much as needed to maintain current spending. In the recent hearing on the topic, they noted that they might not lower list prices at all if commercial plans did not also ban rebates.

Untangling the Web and Paths Forward

Moving forward, it will be important to consider how to maintain or increase innovation in the pharmaceutical market and to align payment with treatment value. Ultimately, any action taken will involve tradeoffs. I believe there are opportunities to lower costs to patients and improve their access to drugs, and hope that these efforts will be combined with rational policies that target drug prices, increase competition, and improve transparency.

Thank you for the opportunity to testify regarding this important topic.

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Testimony of Jane Horvath

Before the US Senate Special Committee on Aging

March 7, 2019

Chairman Collins, Ranking Member Casey and members of the Committee, thank you for the opportunity to speak to the Committee about state efforts to constrain the cost of prescription drugs. I appreciate the leadership of Senator Collins, Ranking Member Casey and this Committee in recent years to highlight the growing strain of prescription drug costs. Aging Committee leadership on drug costs goes back further -- to the late 1980's. Under then-Chairman Senator Pryor, an examination of drugs costs in Medicaid lead to the creation of the Medicaid Prescription Drug Rebate Program (MPDRP) in 1990.

I have worked with states and prescription drug costs for many years. In fact, in 1990, I represented the Medicaid Directors and ran the Association when the rebate program was created. Most recently, I have been working with states since 2016 on prescription drug policy, including Utah, Oregon, Massachusetts, Nevada, California, Vermont, Maryland, Illinois, Minnesota, and New Jersey among others. I work with community groups, legislators, and state agencies.

State Transparency Laws and Proposals

Requiring transparency of the prescription drug market and pharmacy benefits is an important first step. Transparency is one of the few policy areas where a legal challenge can be avoided, depending on how the transparency policy is structured. Drug companies have sued California and Nevada – two of the very first states to enact drug industry transparency laws back in 2017. The California lawsuit is ongoing; the industry dropped the Nevada lawsuit after agreement on how trade secrets data would be protected. Importantly, the Nevada law requires transparency of funding sources for organizations that work with the legislature.

Last year, five states enacted drug manufacturer transparency laws including Oregon and Connecticut. These laws build on the laws of California and Nevada to get more transparency from the drug supply chain and payors – notable pharmacy benefit managers. Increasingly, states are proposing and enacting transparency legislation that requires reporting from insurers and pharmacy benefit managers (PBMs) on net spending on high cost drugs, rebates received by PBMs and the percentage of rebates the PBM passes through to insurers. The information required in the new state laws complements the data on the CMS prescription drug dashboards which summarizes drug spending for Medicaid and Medicare B and D. These dashboards analyze the spending data in a variety of interesting ways, similar to what the states are requiring of commercial insurers.

The results of transparency legislation are available on state websites. Because of the number of states with transparency laws, I do not think that additional states need to enact transparency legislation. States with laws are setting up databases to capture reported information and share it with the public. States without transparency legislation can access the public data that will exist in the 11 states that have transparency laws and programs. States should also explore the use of Memoranda of Understanding to access proprietary data that some states will obtain.[1] I do not think every state should spend scarce resources setting up and maintaining similar databases, and federal initiatives could also obviate the need for more individual state transparency reporting systems. Drug launches and drug price increases are national. Insurer drug costs for a working age population are similar throughout the country – similar enough to see cost trends and identify the most expensive drug products.

Ideas for More Federal Drug Cost and Price Transparency

There are ways the federal government could improve transparency of drug costs, drug spending and manufacturer pricing behavior – improving the ability of policy makers to understand the prescription drug market more fully. The federal government could expand its current Medicare and Medicaid 'Dashboard' framework in the following ways:

- Office of Personnel Management (OPM) health plans and the Veterans Administration (VA) could report drug spending data. The OPM data – federal data on a working age population -- may obviate the need for state-level legislation that captures similar data. In addition to following the format of the CMS dashboards, the OPM data should also mirror the state data elements of drug spending such as breakdown of spend by generic and brand, manufacturer rebates as a percentage of pharmacy spend, and the top 25 most costly drugs.
- It is important to know which prescription drugs in the Medicaid program are rebated at only the flat minimum rebate (no deep discounts in the commercial sector that create a Medicaid best price).[2] This can tell us something about pricing behavior – if rebates increase when there is therapeutic competition, or if there any discounts for new first in class products for instance. Some of this data is proprietary but an oversight committee could request it and distill it.
- It would be helpful to know which drugs, by name, reach the cap on Medicaid rebate liability. The Medicaid rebate captures price increases that exceed growth in the CPI (in addition to the best price and minimum rebates). But manufacturer rebates are capped at 100% of the wholesale cost of a drug.[3] Drugs that hit the rebate cap are drugs that have had very high price increases or years of smaller price increases. The inflation calculation is a bit complex, but the cap on rebate liability means that exorbitant price

[1] Every state has trade secrets protection laws and there is a federal trade secrets protection law as well that prevent public disclosure of proprietary data.
[2] The actual dollar amount of the best price should remain confidential, simply knowing whether there is a best price -- that a manufacturer is offering price concessions to payers or purchasers is the important information.
[3] The Medicaid terminology is Average Manufacturer Price, which comes from a specific calculation, but the AMP is generally similar to the wholesale price for purposes of this testimony.

increases are not effectively recaptured in the rebates.[4] CMS should report which drugs have hit the cap of 100% of the wholesale price. Those drugs can be named since the fact of the price increase and the size of the increase are public information. This Medicaid data would help policy makings more easily see pricing behavior.

Federal Constraints on State Action Beyond Transparency

There are number of federal-level constraints on state action to constrain drug costs and drug spending.

Caselaw: In general state options are limited for taking the next step after transparency -- tackling prescription drug costs because of federal law and federal court rulings. Courts have ruled that states cannot set a price for a brand drug because it violates federal patent law and triggers the supremacy clause of the Constitution. Courts have also ruled that limiting a manufacturer's drug price violates the dormant commerce clause. Case law limits state ability to reference price (to limit the price or cost of a drug based on prices in Europe or Canada) because that has been ruled to violate the dormant commerce clause.

FDA law: In addition to federal case law, federal FDA law currently limits state importation programs to Canada, which will limit how many states can try this approach. For example, Florida's governor just announced intent to get federal permission to import drugs from Canada. There are about 21 million Floridians and about 37 million Canadians. Vermont is working to implement their 2018 importation law. Seven other states have importation proposals before the legislature this year and several governors committed to importation in their election campaigns.

Medicaid law: Federal Medicaid law limits the effectiveness of programs such as the multi-agency drug bulk purchase initiative announced by California's Governor in January. Unlike federal agencies and federal programs whose drug discounts are exempt from the Medicaid Best Price calculation[5], the drug discounts of state agencies and programs are included in the Best Price calculation. While federal programs can get deep price concessions, state agencies cannot. State agencies will only get discounts that do not set a new, low Medicaid best price. Regardless how large a state's drug purchasing pool is and how much volume can be purchased, a state cannot do better than the basic Medicaid discount of roughly 23%. Importantly, state taxes support the pharmacy benefit of 25-30% of the residents of the states I've worked with.[6]

Interestingly, federal law limits state ability to drive deep discounts -- even though a state Medicaid program discount/rebate negotiation is exempt from the manufacturers' calculation of best price. Federal law prohibits state Medicaid programs from managing a drug benefit formulary in the same way that commercial insurers can. Private insurers can create a restrictive formulary -- the insurer can

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[4] The cap on rebate amounts was included in the Medicare Part D law. It made sense at the time because small annual price increases could over ten years or so, cause the rebate to by more than the price of the drug. However, price increases today are bigger and more frequent than they were 15 years ago.

[5] Manufacturers report to CMS their best price in the US market to any purchaser or payor. That best price discount then has to be given for all Medicaid utilization of that product in all states. Medicaid covers about 71 million people, to creating a new best price for a drug is significant for a manufacturer. Generally speaking, a best price is created to the extent that the discount exceeds the base Medicaid rebate of 23% of the wholesale price.

[6] Of course the actual percentage is state-specific based on Medicaid, state, local employees, dependents and retirees, prisons, public health, higher education and public education employees and dependents.

choose one drug in a class rather than its competitors based on the price concession the manufacturer offers. Such formulary management can drive manufacturer discounts or rebates which allows health plans to better manage costs.

What States Can Do to Manage Drug Costs

Beyond transparency, state options to constrain prescription drug spending are quite limited because of decades old laws and court decisions. There are two ways I can think where a state could be successful in drug cost containment policy and avoid the range of legal limitations. Importation is one idea and creating statewide upper payment limits for certain high cost drugs is another. I wrote the model acts for these two approaches that states are using. These two approaches achieve what I believe is the single most important aspect of constraining drug spending and making drugs more affordable for patients – getting a lower cost product to the pharmacy counter.

For importation, the import is distributed to participating purchasers – hospitals, clinics, pharmacies. The imported price of the product is public. Insurers will only reimburse pharmacies and providers at the import price. Pharmacies can only charge patients the import price and the insurer pharmacy benefit is keyed to the import price. States administer the program to ensure compliance with global supply chain safety and to ensure that distributors and dispensers limit charges to the imported price. The FDA announced its desire to import certain generic drugs and biologics to create market competition in the U.S. State policymakers also view importation as a way to create price competition.

For a state all-payer upper payment limit (UPL) program, the law will do statewide and uniformly, what every insurer, Medicaid program, state employee program, and large hospital system do for every drug and every medical service – they set a payment rate. They do not pay charges. Health care payment rate setting has been the standard approach in US health care for decades. Payment rate setting drives providers and pharmacies to lower their costs. A statewide, obligatory UPL for certain high cost drugs will drive negotiations up the supply chain to the manufacturer – just as payment rates do today. Seven states have UPL bills in the legislature this year.

Manufacturers have never sued over patent law violations for the federal 340B program, Medicare payment rates or Medicaid drug payment rates. That is decades of acceptance of the idea of upper payment limits in the US healthcare system. Manufacturers never sued Maryland over its statewide, all payer hospital rate system when that required negotiation about the cost of new drugs that would cause a hospital to lose money under the statewide payment rate. No manufacturer has every sued on the basis of the dormant commerce clause when state-run facilities force negotiations on price up the drug supply chain because they can't afford an important drug product.

States would prefer to tackle drug costs more directly than importation or statewide upper payment limits, but there are few options that can really change the cost trajectory.

How Congress Can Help States Innovate on Drug Cost Policies

Congress can help states innovate and test new drug cost containment strategies with a few changes to federal law:

- In the Food Drug and Cosmetic Act, expand countries from which a state may import to the EU, in addition to Canada, for state-administered programs of importation. Allow these state programs to import biologics, which are safely imported today.
- Clarify that patent law does not limit states' ability to protect the health of residents in the regulation of the cost or price of patented products.
- Clarify that any state has authority to regulate in-state commerce even when that regulation causes a global, national or regional out of state company to take specific actions relative to the product that is sold in the particular state.
- Exempt state government drug cost control initiatives and programs from Medicaid best price calculations – extending the same privilege to states from which federal agencies and programs benefit.
- Allow Medicaid rebates to fully capture the impact of manufacturer pricing behavior by eliminating the cap on rebate amounts.

Thank you for the opportunity to share my thoughts on this very important public policy issue.

Statements for the Record

Statement on
"The Complex Web of Prescription Drug Prices"

Submitted to the
Senate Special Committee on Aging

March 7, 2019

America's Health Insurance Plans (AHIP) is the national association whose members provide coverage for health care and related services to millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers.

We thank the Committee for focusing on out-of-control prescription drug prices. Rising drug prices impose a heavy burden on all Americans—this is a direct result of high list prices determined solely by drug companies. We look forward to working with committee members to advance market-based solutions that hold drug makers accountable for high list prices and provide relief to American families from soaring prices for prescription drugs.

In order to make life-saving drugs available and affordable for patients, health insurance providers and our pharmacy benefit manager (PBM) partners negotiate with drug makers. These savings are passed along to patients and consumers through lower premiums and out-of-pocket costs. But the lack of transparency in how prices are set or why they go up multiple times a year creates a barrier to developing new solutions to lower drug prices. Additional legislative and regulatory actions are needed to make prescription drugs more affordable for everyone.

Our statement focuses on:

- The reality that the prescription drug pricing process is dictated by the original list price of a branded drug—which is determined solely by the drug maker, not by the market or any other participant in the pharmaceutical supply chain;

- Key areas where we support efforts by Congress and the Administration to use market-based solutions, with a systemwide focus, to put downward pressure on prescription drug prices through competition, consumer choice, and open and honest drug pricing;

- Our support for recent improvements to the Medicare Part D prescription drug program and enhanced private sector negotiation tools in Medicare; and

- Our concerns with a proposed rule, published in February 2019 by the Department of Health and Human Services (HHS). This proposal would dramatically change how Part D plans, Medicaid managed care plans, and their contracted PBMs negotiate discounts with drug manufacturers. By the government's own estimates (which we believe may significantly understate the actual impacts), the proposal would raise premiums on America's seniors by 25 percent, increase taxpayer costs by nearly $200 billion, and give away tens of billions of dollars to Big Pharma—while doing nothing to address the core problem of high drug prices in this country.

The Problem Is the Price

Out-of-control prescription drug prices have profound consequences for all Americans. Outrageous drug prices harm patients who cannot afford life-saving medications, consumers who pay higher and higher premiums because of higher and higher drug prices, employers who have fewer resources to devote to employee wages, and hardworking taxpayers who fund public programs like Medicaid and Medicare.

We urge the Committee to recognize that drug costs, premiums, employer burdens, and taxpayer expenses are dictated by the list price of a branded drug—which is determined solely by the drug company, not by the market or any other participant in the pharmaceutical supply chain. Already this year, drug companies have raised the prices of hundreds of medicines—including top-selling drug Humira.[1] The price of Evzio, which is used to treat suspected opioid overdoses, increased

[1] https://www.axios.com/drug-price-increases-2019-fba56e62-8737-40c5-8cd7-57e9d5bbf5f6.html

652 percent from 2014 to 2017. And the price of antidepressant Wellbutrin increased nearly six-fold in that same timeframe.[2]

The problem with excessively high list prices is clearly illustrated by data generated by the Institute for Clinical and Economic Review (ICER). ICER is an independent organization that develops value-based price benchmarks to help inform negotiations by PBMs and promote the use of high-value drugs. These benchmarks, which are based on ICER's evaluation of the value of specific drug products, recommend discounts that are needed, relative to the drug's list price, to meet common thresholds for cost-effectiveness. For example, ICER recommends that a 62-80 percent discount is justified for biologics treating eosinophilic asthma, that a 25-46 percent discount is justified for calcitonin-gene-related peptide (CGRP) blockers used for migraine prevention, and that a 50-75 percent discount is justified for using luxturna for childhood blindness. These estimates, by measuring the extent to which list prices exceed the value of prescription drugs, clearly demonstrate that the problem is the price.

Congress needs to address this reality—that **"The Problem Is the Price"**—as part of any strategy for reducing pharmaceutical costs for the American people. The crisis of high-priced drugs is a direct consequence of pharmaceutical companies taking advantage of a broken market for their own financial gain at the expense of patients. The lack of competition, transparency, and accountability in the prescription drug market has created extended, price-dictating monopolies with economic power that exist nowhere else in the U.S. economy. As a result, everyone pays more—patients, businesses, taxpayers, hospitals, doctors, and pharmacists.

Market-Based Solutions for Reducing Drug Prices

Bold steps are needed, at both the legislative and regulatory levels, to hold drug makers accountable for high list prices and ensure that the American people have access to affordable medications. With solutions that deliver real competition, create more consumer choice, and ensure open and honest drug prices, we can deliver more affordable pharmaceutical products—while at the same time protecting and supporting innovations to deliver new treatments and cures for patients.

Below we provide a high-level overview of key areas where we support efforts by Congress and the Administration to put downward pressure on prescription drug prices. As the Committee

[2] https://www.ahip.org/then-vs-now/

continues to examine drug pricing, we look forward to working with you on these and other issues.

Promoting Generic Competition

Removing barriers to the availability of generic drugs is a critically important step toward lowering out-of-pocket prescription drug costs for the American people. We appreciate that the Administration has prioritized the review and approval of applications for generic drugs, and we applaud Committee members for your leadership in developing bipartisan legislative proposals that would promote generic competition.

We strongly support the "Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act." This bipartisan bill offers common sense reforms that would discourage brand name drug makers from blocking the availability of generic drugs by abusing Risk Evaluation and Mitigation Strategies (REMS) that are otherwise required by the Food and Drug Administration (FDA) to promote patient safety. If this legislation is enacted, branded drug makers will no longer be able to hide behind REMS and limited distribution arrangements to restrict access to adequate samples of reference drugs and impede the development of lower-cost generic competitors.

We also strongly support bipartisan legislation that would give the Federal Trade Commission (FTC) enhanced authority to block "pay-for-delay" agreements under which prescription drug patent infringement claims are settled with a potential generic competitor agreeing (after receiving something "of value") not to research, develop, manufacture, market, or sell the product in question. Halting these anti-competitive settlements will remove a barrier to competition and expand the availability of lower-cost generic drugs and biosimilars.

Additionally, we believe it is important to preserve the Inter Partes Review (IPR) process at the U.S. Patent and Trademark Office. The IPR process plays an important role in invalidating patents that do not represent true innovation and should not have been issued in the first place. Weakening this process would effectively extend the original patent monopoly for pharmaceutical and biological products and result in significantly higher prices for consumers.

We support congressional action on revisions to the United States-Mexico-Canada Agreement (USMCA). However, in its current form, we have serious concerns that this proposed trade agreement includes market exclusivity provisions that would benefit brand name drug manufacturers at the expense of lower cost generics. Specifically, the proposed USMCA text

includes many monopoly protections and related anti-competitive provisions—such as extended biologics exclusivity, broad market exclusivities for brand name drugs, and patent term extensions—that are likely to exacerbate the problem of high drug prices and will increase drug prices for patients and consumers. At the same time, the USMCA lacks important provisions necessary to assure a proper balance between innovation and competition—such as incentives for generic and biosimilar availability. In fact, as currently written, certain provisions of the USMCA appear inconsistent with U.S. law—by failing to incorporate pro-competitive provisions included in the Hatch-Waxman amendments and the Biologics Price Competition and Innovation Act (BPCIA). For all these reasons, we recommend that Congress address these highly problematic provisions and incorporate public policies that promote greater competition which, in turn, can facilitate patient access to less expensive generics and biosimilars.

Creating a Robust and Competitive Marketplace for Biosimilars

Biosimilars offer great promise in generating cost savings and increasing patient access to needed treatments and therapies. To achieve this promise, it is important to promote a vibrant and competitive biosimilars market and ensure that providers and patients have unbiased information about the benefits of biosimilars. Just as with generic medications, a truly competitive biosimilars market will mean greater use of these products which, in turn, will drive down costs and increase patient access.

AHIP supports key provisions of the FDA's Biosimilars Action Plan,[3] which takes important steps toward promoting competition and affordability in the market for biologics and biosimilar products. Our recommendations for the Action Plan include promoting regulatory clarity by finalizing FDA guidance related to interchangeability, improving efficiency in the biosimilars product development and approval process, and developing effective communication tools and resources to educate providers and patients on the safety and efficacy of biosimilars. We also support legislation to reduce the exclusivity period for brand name biologics and enhanced oversight of "pay-for-delay" arrangements that prevent generics and biosimilars from coming to market.

Increasing Transparency Around Pharmaceutical Prices

Requiring greater transparency on prescription drug prices is an important step toward ensuring that consumers have the information they need to make informed health care decisions.

[3] https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm613761.pdf

Currently, many patients lack drug pricing information for making informed choices about their treatment options. Increasing access to pricing information can help patients minimize their out-of-pocket costs, enabling them to compare different treatment options and help them identify lower cost, but equally effective, options such as generic drugs or biosimilars.

We believe drug makers should be required, as part of the FDA approval process, to disclose information regarding the intended launch price, the use of the drug, and direct and indirect research and development costs. After approval, drug makers should provide appropriate transparency into list price increases.

In addition to empowering consumers, openly disclosing drug prices will bring additional public attention to drug price increases, which will discourage drug makers from raising their prices year after year—often multiple times a year—without justification. Government leaders, regulators, consumers, and insurance providers deserve to know how prices are set and what causes them to go up. By understanding the market dynamics of why prices are going up, we can work together to mitigate those effects.

We support the Administration's proposal to require disclosure of drug list prices in direct-to-consumer (DTC) television ads. We also recommend that this proposed requirement be broadened to apply to all ads by drug companies, including those in newspapers, print publications and on the web. We further suggest that drug pricing transparency requirements—including disclosure of a drug's list price—be extended to include drug makers' marketing or detailing materials distributed to physicians and other prescribers.

Preserving Recent Improvements to Medicare Part D and Enhanced Private Sector Negotiation Tools in the Medicare Program

Since 2006, the Medicare Part D program has been a successful model of a public-private partnership where Part D plans have effectively negotiated lower drug prices and costs so that tens of millions of seniors and individuals with disabilities have affordable and meaningful access to prescription drugs at consistently low and stable premiums year-over-year. However, rising drug prices threaten the long-term stability of the program. That is why AHIP strongly supported improvements that Congress approved last year as part of the Bipartisan Budget Act of 2018, including increased drug maker liability under the coverage gap discount program. Efforts to reverse these improvements, if successful, would increase costs for seniors and taxpayers, and

provide a massive bailout for the pharmaceutical industry.[4] We urge the Committee to reject any such efforts in the 116th Congress.

In our many comments on regulatory proposals by the Centers for Medicare & Medicaid Services (CMS), we have consistently advocated for greater leverage for Part D plan sponsors and health insurance providers to negotiate more savings from drug makers and for more flexibility to use private sector formulary tools to deliver safe, appropriate, and cost-effective care for Medicare enrollees.

Most recently, we expressed support for CMS proposals that would expand the use of clinically appropriate, evidence-based medical management and formulary tools for certain high-cost drugs in Part D; employ such tools for physician-administered medications covered by Medicare Advantage plans; and apply well-tested beneficiary protections and rigorous CMS oversight processes to ensure patients always have access to the drugs they need. These tools are widely used in the private sector outside of the Medicare program and have been used successfully for most drugs covered by Part D since the program's inception in 2006. In addition, such tools would allow plan sponsors to ensure safe and appropriate care while negotiating lower drug costs on behalf of Medicare beneficiaries.

We also support recent CMS guidance that allows for indication-based formularies and for streamlining mid-year formulary changes relating to generic drugs in the Medicare Part D program. These added flexibilities allow health insurance providers to continue to keep premiums and out-of-pocket costs low by designing innovative formularies and quickly responding to high prices and price increases imposed by drug makers.

We appreciate CMS' efforts to reduce prices for prescription drugs covered by the traditional Medicare program under Part B—including a proposal that would test changes to payments for certain Part B-covered drugs and biologics under an international pricing index (IPI) model. By seeking to lower prescription drug costs in Medicare Part B and addressing flawed incentives in the current payment system, this proposal holds promise in advancing the goals of improved access and affordability of medicines for millions of seniors and people with disabilities, especially for those drugs where no therapeutic alternatives or competition exists.

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[4] Oliver Wyman estimates that reducing the manufacturer discount from its current 70 percent to 63 percent would increase federal government spending by $4.45 billion and beneficiary premiums by $4.05 billion, resulting in $8.5 billion additional drug manufacturer revenue. https://www.oliverwyman.com/content/dam/oliver-wyman/v2/publications/2018/november/Part-D-Coverage-Gap-Report-Final.pdf

Proposed Rebate Restrictions Would Undermine Savings for Patients and Taxpayers

The HHS Office of Inspector General has released a proposed rule,[5] published in the February 6 *Federal Register*, which would exclude prescription drug rebates paid by drug makers to PBMs, Medicare Part D plans, and Medicaid health plans from safe harbor protection under the Anti-Kickback Statute (AKS). Instead, to comply with the AKS, negotiated discounts would need to be paid through a new, more complex, and untested "charge-back" structure involving PBMs, plans, manufacturers, and chain and community drug stores.

We are working closely with our members to develop comments on this rule by the April 8 deadline. We look forward to sharing our detailed comments with the Committee. That said, we are extremely concerned that, based on estimates for the next decade released by the CMS Office of the Actuary,[6] the proposal would raise premiums for seniors by 25 percent—about $58 billion—over the next decade, increase taxpayer costs by almost $200 billion, and give away tens of billions more dollars to the pharmaceutical industry while increasing drug spending by $137 billion. Simply put, by the government's own estimates, this proposed rule is much more likely to increase drug prices and costs rather than have the intended effect.

The government's own actuaries note how, for example, drug makers would likely use the opportunity created by the HHS rebate rule to claw back money to offset their responsibility for reducing seniors' burden in the donut hole.[7] Moreover, our view is that actual adverse impacts (reflecting numerous operational challenges, legal questions, and other issues) could be far worse for seniors, taxpayers, and other stakeholders, while at the same time resulting in even greater giveaways to Big Pharma.

We believe the proposal is the product of nonstop efforts by the pharmaceutical industry to deflect attention away from outrageously high prices by convincing Americans that health insurance providers and PBMs are the problem, acting as so-called "middlemen." AHIP's health insurance provider members and our PBM partners are not middlemen: our members use their bargaining power to negotiate larger discounts from drug makers to save seniors and other patients about 50 percent annually on their prescription drug and related medical costs.[8] If health insurance providers and PBMs were not doing this important work, drug prices and Medicare

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[5] https://www.govinfo.gov/content/pkg/FR-2019-02-06/pdf/2019-01026.pdf
[6] https://aspe.hhs.gov/pdf-report/prescription-drug-pricing-aspe-resources-related-safe-harbor-rule
[7] https://aspe.hhs.gov/system/files/pdf/260591/OACTProposedSafeHarborRegulationImpacts.pdf
[8] https://www.pcmanet.org/the-return-on-investment-roi-on-pbm-services/

enrollee costs would undoubtedly be far higher. Projections show that over the next decade, we will save consumers and taxpayers more than $650 billion on drug benefit costs.[9]

Savings from rebates go directly to consumers, resulting in lower premiums and out-of-pocket costs for millions of hardworking Americans. These savings may be imperiled by well-intentioned but misguided actions like the HHS proposed rule. This proposal would increase, not decrease costs for taxpayers—limiting important negotiating tools without introducing any new leverage for lower prices, and offering absolutely no incentive for Big Pharma to ever reduce their drug prices.

From the start, the focus on rebates has been a distraction from the real issue—the problem is the price. It bears repeating that drug makers alone set their drug prices, they alone increase prices, and they alone can decide to reduce the price of their drugs. And, despite the best efforts of the Administration, already this year more than three dozen drug makers have raised their prices on hundreds of medications.[10]

Health insurance providers are part of the solution. We believe the Administration should reconsider the unintended impacts of this proposed rule, and instead take actions that will lower drug prices by holding drug makers accountable for the prices they set.

Conclusion

Thank you for considering our support for market-based solutions to address the pharmaceutical cost crisis. As Congress considers legislative options, we look forward to working with you to make prescription drugs more affordable. Everyone deserves access to the medications they need at a price they can afford. We should not have to choose between innovation and affordability. With the right solutions and genuine collaboration, we can have both.

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[9] https://www.pcmanet.org/our-industry/
[10] https://www.reuters.com/article/us-usa-drugpricing/drug-companies-greet-2019-with-u-s-price-hikes-idUSKCN1OW1GA

Senate Special Committee on Aging

Hearing on: "The Complex Web of Prescription Drug Prices, Part II: Untangling the Web and Paths Forward"

March 7, 2019

Statement for the Record
Submitted by ASHP

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ASHP Statement for the Record
Senate Special Committee on Aging: "The Complex Web of Prescription Drug Prices, Part II: Untangling the Web and Paths Forward"
March 7, 2019

ASHP (American Society of Health-System Pharmacists) respectfully submits the following statement for the record to the Senate Committee on Finance hearing on "The Complex Web of Prescription Drug Prices, Part II: Untangling the Web and Paths Forward."

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's nearly 50,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP's vision is that medication use will be optimal, safe, and effective for all people all of the time. A primary tenet of that vision is access to affordable medications needed to save or sustain lives. Addressing the issue of skyrocketing drug prices, including excessive price increases on commonly used generic medications, is one of ASHP's highest and longstanding public policy priorities.

According to a Kaiser Health Tracking Poll, 1 in 4 Americans cannot afford their medications.[1] For seniors, 64.6% of respondents to a Truven Health Analytics–NPR Health Poll indicated that cost was the reason for not filling a prescription.[2] Poor access to medications can lead to increased morbidity and mortality, and can cause healthcare costs to increase. This is especially concerning when considering Medicare Part D enrollees, who take an average of 54.5 prescriptions per year.[3]

ASHP has been proactively addressing challenges related to the rapid increase of prescription drug pricing on several fronts, including working with like-minded stakeholders and educating members of Congress about the unsustainable burdens faced by patients, healthcare providers, and the entire healthcare system.

ASHP is a lead member of the Steering Committee of the Campaign for Sustainable Rx Pricing (CSRxP), a coalition of prominent national organizations representing physicians, consumers, payers, hospitals, health systems, and patient advocacy groups. CSRxP has developed a policy platform promoting market-based solutions supported by three pillars: competition, value, and transparency.

The goal of the campaign is to identify policy options that have bipartisan support and, therefore, a greater likelihood of passage. To that end, CSRxP focuses on policies to incentivize a more competitive marketplace to help stimulate lower drug prices. The campaign has also expressed support for efforts to loosen restrictions that prevent generic drug companies from obtaining the samples necessary to manufacture a competing product.

The price increases have placed enormous budgetary pressure on healthcare organizations, including hospitals and health systems. ASHP, along with the American Hospital Association (AHA) and the

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[1] DiJulio, Bianca, et al. "Kaiser Health Tracking Poll: August 2015." The Henry J. Kaiser Family Foundation, The Henry J. Kaiser Family Foundation, 20 Aug. 2015, www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-august-2015/. Accessed February 10, 2019.
[2] Truven Health Analytics®-NPR "Health Poll: Prescription Drugs." June 2017, https://truvenhealth.com/Portals/0/Assets/TRU_18156_0617_NPR_Poll_Prescription_Drugs_FINAL.pdf. Accessed March 5, 2019
[3] Medpac June 2018 Data Book: http://www.medpac.gov/docs/default-source/data-book/jun18_databooksec10_sec.pdf?sfvrsn=0, p.170. Accessed March 5, 2019.

ASHP Statement for the Record
Senate Special Committee on Aging: "The Complex Web of Prescription Drug Prices, Part II: Untangling the Web and Paths Forward"
March 7, 2019

Federation of American Hospitals (FAH), recently released a report on the impact that the cost of and access to prescription drugs are having on hospital budgets and operations.

Specifically, the report showed that:

- Average total drug spending per hospital admission increased by 18.5% between fiscal year (FY) 2015 and FY2017.
- Outpatient drug spending per admission increased by 28.7%, while inpatient drug spending per admission increased by 9.6%, between FY2015 and FY2017.
- Hospitals experienced price increases of over 80% across different classes of drugs, including those for anesthetics, parenteral solutions, and chemotherapy.
- Over 90% of surveyed hospitals reported having to identify alternative therapies to manage spending.
- One in 4 hospitals had to cut staff to mitigate budget pressures.[4]

ASHP does not collect, store, or report drug pricing information. However, we continually hear from pharmacy leaders in hospitals and health systems that sudden, inexplicable, and unpredictable price increases in connection with some of the most commonly used, longstanding generic medications are becoming more prevalent — and are occurring on a nationwide basis.

The upward trend in medication pricing, coupled with sudden price spikes, can be particularly problematic for seniors, many of whom rely on a fixed income. According to the Kaiser Family Foundation, on average, seniors enrolled in traditional Medicare spent $4,400 out-of-pocket annually for premiums and other costs associated with their healthcare. Prescription drug costs added an additional $300 per beneficiary, although individuals with multiple acute or chronic conditions faced much higher medication costs.[5] These costs continue to rise unabated.

As the committee is aware, drug prices are straining the Medicare program. According to MedPAC, drug spend for the Part D program alone rose 10.9% between 2009 and 2015.[6] The increase in Part B expenditures during the same period is even higher. Neither the Medicare program nor the seniors it covers can continue to absorb these increases year over year.

As there is no single solution to spikes in the prices of certain drugs, there is no single cause either. In this statement, we address four additional issues as they relate to drug pricing: competition, Risk

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[4] NORC at the University of Chicago. Recent Trends in Hospital Drug Spending and Manufacturer Shortages (2019). https://fah.org/fah-ee2-uploads/website/documents/AHA_Drug_Pricing_Study_Report_FINAL_01152019.pdf. Accessed 25 Feb. 2019.

[5] Kaiser Family Foundation, *How Much is Enough? Out-of-Pocket Spending Among Medicare Beneficiaries: A Chartbook* (July 21, 2014), available at https://www.kff.org/report-section/how-much-is-enough-out-of-pocket-spending-among-medicare-beneficiaries-section-1/.

[6] Medpac June 2018 Data Book: http://www.medpac.gov/docs/default-source/data-book/jun18_databooksec10_sec.pdf?sfvrsn=0, p.170. Accessed March 5, 2019.

Evaluation and Mitigation Strategies (REMS), Direct and Indirect Remuneration (DIR Fees), and the 340B Drug Pricing Program.

COMPETITION

In particular, ASHP would like to learn more about the marketplace dynamics that could contribute to this issue, as we have worked diligently to address the issue of drug shortages for nearly 15 years. Although drug shortages are caused by a number of factors, we have observed that drugs in short supply that are made by only one or two manufacturers often result in higher-than-normal prices. If, for example, there is a lack of competition in the generic marketplace, we urge the committee to look at ways to stimulate more marketplace presence. ASHP supports bills such as S. 64, the "Preserve Access to Affordable Generics and Biosimilars Act." This bipartisan bill would potentially increase competition by prohibiting companies from engaging in "pay-to-delay" tactics to stifle generic and biosimilar entry into the market.

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

ASHP recognizes that there may be limited circumstances in which constraints on the traditional drug supply system may be appropriate for reasons of patient safety, including through the use of manufacturer-driven REMS. However, we believe that REMS should never be used to artificially inflate drug prices, nor should REMS interfere with the professional practice of pharmacists, physicians, nurses, and other providers. We believe that there may be current cases in which a manufacturer-driven REMS using restricted distribution is causing higher prices for those drugs, having adverse effects on patient access, and delaying treatment. In some cases, there may be evidence to suggest that the use of restricted or limited distribution channels has resulted in the inability of a potential competitor to acquire enough of a drug to conduct the required testing to bring a generic competitor to market. For this reason, ASHP thanks Chairman Grassley for introducing S. 340, the "Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019." The CREATES Act will help ensure that brand-name pharmaceutical companies cannot manipulate regulatory rules to prevent competition, which is essential for patient access to affordable medications. Additionally, we recommend that Congress require the Food and Drug Administration (FDA) to investigate restricted distribution under a REMS as a means to artificially increase drug prices and limit access to critical medications. Restricting distribution of medications is often a means to push patients to a specific purchasing channel, which in some cases increases not only their out-of-pocket costs, but also systemic costs. Further, restricted distribution networks can complicate patient access to critical medications, potentially disrupting care.

DIRECT AND INDIRECT REMUNERATION FEES (DIR Fees)

Many factors contribute to high drug product costs; addressing the problem is made difficult by lack of transparency about the marketplace for those products. For example, DIR fees and other rebates negotiated by pharmacy benefit managers (PBMs) make it difficult to determine the actual cost of a drug. DIR fees are a growing nationwide concern among pharmacies that dispense medications in a community pharmacy or outpatient clinic setting. Created under the Medicare Part D Program, DIR fees were originally intended as a way for CMS to account for the true cost of the drug dispensed, including any manufacturer rebates. Often these rebates were unknown until the drug was dispensed and the claim adjudicated. Moreover, the fees themselves, which are often arbitrary in nature, have

mushroomed over the past decade, to the point that pharmacies regularly see annual DIR fee totals in the tens of thousands of dollars.

Recently, a concerning trend has emerged in which PBMs have begun to charge DIR fees to their pharmacy providers. Under this scenario, PBMs are inappropriately applying their own plan performance measures as a way to assess fees on pharmacies. This is problematic for the following reasons:

- It is an arbitrary and unintended application of quality measures meant for total plan performance as opposed to pharmacy-level metrics.
- The quality measures applied tend to be based on maintenance medications such as blood pressure medications or medications used to treat diabetes. These measures were never intended to be applied to specialty medications or to other specialized disease states such as oncology, yet PBMs assess DIR fees against the gross reimbursement for all prescriptions received by pharmacy providers, not just maintenance medications.
- Pharmacy providers are essentially being penalized with backdoor fees without any requirement that PBMs define, justify, or explain these charges to providers and to CMS.

DIR fees assessed on pharmacies providing specialty medications have been especially hard-hit, due to the fee structure. Fees could be a flat rate of per dollar per claim or a percentage (typically 3–9%) of the total reimbursement per claim. Using the percentage-based structure, the fees would increase markedly for specialty drugs, which are typically much more expensive than maintenance medications, sometimes resulting in thousands of dollars. A 9% fee on a drug costing $100,000 is $9,000. Additionally, these fees are assessed retroactively, sometimes months after the claim has been adjudicated, providing no recourse for the pharmacy impacted by the assessment.

The result of imposing DIR fees has led to higher cost-sharing responsibilities for Medicare beneficiaries, which have, in turn, caused more of these beneficiaries to enter the Part D donut hole, where the patient is solely responsible for the cost of the drug. Along with the higher costs absorbed by patients, adherence rates tend to be lower among Medicare beneficiaries who are in the donut hole and may not have the financial resources to pay for their medications. This is in stark contrast to the very reason DIR fees targeting manufacturer rebates were created — so that savings could be passed on to patients.

Pharmacies are not alone in their concern. In January 2017, CMS published a fact sheet expressing concern over DIR fees and cited those fees as contributing to increased drug costs, which, in turn, increased patients' out-of-pocket spending and Medicare spending overall.[7] Additionally, questions remain as to whether Part D plan sponsors have the authority to assess these fees on pharmacies. There are no references to DIR fees collected on pharmacies in either the Part D statute or corresponding CMS regulations.

ASHP's professional policy on DIR fees is as follows:

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[7] Fact sheet Medicare Part D – Direct and Indirect Remuneration (DIR). Centers for Medicare & Medicaid Services, 19 January. 2017, https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir. Accessed February 10, 2019

To advocate that payers and pharmacy benefit managers be prohibited from recovering direct and indirect remuneration fees from pharmacies on adjudicated dispensing claims; further,

To oppose the application of plan-level quality measures on specific providers, such as participating pharmacies.[8]

THE 340B DRUG PRICING PROGRAM

For 25 years, the 340B Drug Pricing Program has allowed safety-net hospitals "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." This program has been essential to expanding access to lifesaving prescription drugs and comprehensive healthcare services to low-income and uninsured individuals, at no cost to the federal government. *The federal 340B program is not causing high drug prices*. The program accounts for less than 5% of annual drug purchases in the United States, while safety-net providers give 30% of the care. There are many contributing factors to higher drug costs, but there is no objective evidence that the program has increased overall drug pricing. In fact, the 340B program is revenue-neutral, benefiting patients without increasing costs for federal payers.

The federal 340B program enables these hospitals to serve their communities by providing vital care such as:

- Free or lower-cost medications to patients.
- Programs to increase medication adherence, including clinical pharmacy services to high-risk patients who are on multiple and/or complex medications.
- Increased access to primary care.
- Screenings and preventive care services to detect health problems early and decrease morbidity and mortality, as well as to decrease healthcare costs and hospital admissions.

The federal 340B program is at risk because of a recent change in Medicare payment policy that reduces payment from average sales price plus 6% to average sales price minus 22.5%. Cuts of this magnitude undermine the intent of the program, reducing resources that hospitals use to expand access to care and services to vulnerable communities. Given the increasingly high cost of pharmaceuticals, the federal 340B program provides critical support to the entities eligible to participate in the program.

CONCLUSION

ASHP thanks the Special Committee on Aging for holding this important hearing. ASHP remains committed to working with Congress and industry stakeholders to ensure that patients have affordable access to lifesaving and life-sustaining medications.

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[8] ASHP Policy 1814, *Direct and Indirect Remuneration Fees.*

March 7, 2019

The Honorable Susan M. Collins
Chairman
U.S. Senate Special Committee on Aging
G31 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Bob Casey
Ranking Member
U.S. Senate Special Committee on Aging
G31 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Collins and Ranking Member Casey:

The Healthcare Leadership Council (HLC) appreciates the opportunity to submit this letter for the U.S. Senate Special Committee on Aging's hearing on "The Complex Web of Prescription Drug Prices."

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

Competition and Innovation

The U.S. healthcare system has seen an increase in the cost of prescription drugs which has adversely affected patients, providers, payers, and other healthcare stakeholders. Increases in drug prices are often due to the lack of competition in the prescription drug marketplace. As a diverse coalition of healthcare stakeholders across the U.S. healthcare system, we believe innovation is essential to increasing market competition to deliver affordable, cutting-edge drug therapies to the public. HLC believes policies that encourage competitive markets and support innovation will lower drug costs and improve access to treatment. Additionally, competition from generic drugs is critical to lowering drug prices. HLC supports a continuation of streamlining The Food and Drug Administration's (FDA) responsibilities and processes, which would include decreasing the backlog of generic drug approvals at the FDA and broadening FDA authority to accelerate review and approval for new generic drugs. Addressing barriers to and encouraging the entry of new generic drugs into the market will create more competition and help to lower drug prices.

Promoting Value-Based Care

HLC supports a shift towards a value-based system that pays based on value versus volume. In a value-based system, payment for medications is tied to patient outcomes and achieving clinical targets. A value-based payment system creates a disincentive for inappropriate prescribing practices and overutilization, protecting both patient and federal healthcare dollars. However, the adoption of value-based systems, including for prescription drugs, has been stifled by laws designed to discourage inappropriate behavior in a fee-for-service payment model. The most notable barriers in our current healthcare system, the physician self-referral law ("Stark Law"), and the Anti-Kickback Statute require modernization as our healthcare system shifts from volume-based care to increasing the value of care. Modernization of federal fraud and abuse laws will enable pro-patient, value-focused collaboration among payers, providers, and manufacturers.

Another regulatory barrier is the Medicaid Best Price rule requiring drug manufacturers to offer the Medicaid program the lowest price negotiated with any other buyer. This requirement can deter companies from entering into value-based contracts. To utilize value-based contracting, manufacturers must be able to work with providers and health plans to assess the efficacy of a certain drug in a clinical setting and then set prices based on the results. Under current regulations, if a manufacturer sets a substantially discounted price for a drug while waiting for an evaluation of patient outcomes, that artificially lowered price would have to be offered to the Medicaid program. This creates a disincentive for pharmaceutical companies to accept increased risk in value-based contracting and thus, decreases patient access to innovative drug therapies.

Innovation, competition, and a collaborative environment for payers, providers, manufacturers, and patients are conduits for lowering prescription drug costs for all Americans. Thank you for examining this important issue and please feel free to reach out to Tina Grande, Senior Vice President for Policy, at (202) 449-3433 or tgrande@hlc.org with any questions.

Sincerely,

Mary R. Grealy
President

Written Statement of the

Pharmaceutical Care Management Association
325 7th Street, N.W.
Suite 900
Washington, DC, 20004

Submitted to the

UNITED STATES SENATE
SPECIAL COMMITTEE ON AGING

"The Complex Web of Prescription Drug Prices, Part II: Untangling the Web and Paths Forward"

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Introduction

The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided through Fortune 500 employers, health insurers, labor unions, Medicare, Medicaid, and the Federal Employees Health Benefits Program (FEHBP).

PBMs are the primary advocate for consumers and health plans in the fight to keep prescription drugs accessible and affordable. PBMs negotiate on behalf of consumers, and work to keep a lid on overall costs for prescription drugs with market-based tools that encourage competition among drug manufacturers and pharmacies, and incentivize consumers to take the most cost-effective and clinically appropriate medication.

By leveraging competition among manufacturers, PBMs save patients and health plans $123 per prescription, and will negotiate prescription drug costs down $654 billion over the ten years ending 2025.[i]

PBMs manage Medicare Part D drug benefits through insurers, either as contractual service providers to stand-alone Prescription Drug Plans (PDPs) or Medicare Advantage plans that offer prescription drug coverage (MA-PDs).

PBMs are proud of their performance in Part D. PBMs and Part D sponsors have kept overall program costs 30 percent below original government projections, offered beneficiaries lower-than-expected premiums, and generated high levels of generic utilization while providing broad choice of drugs and access to over 60,000 pharmacies, all while attaining a continually high rate of beneficiary satisfaction.

PBMs Negotiate to Keep Drug Spending Manageable

The most recent available data, which is for years 2016 and 2017, show that the overall growth in spending for all prescription drugs has been low,[ii] tallying 1.4% and -0.3% for 2016 and 2017, respectively. Drug industry stakeholders rightly trumpet such figures to show the success of private-sector negotiation in bringing spending discipline to the prescription drug market.

However, the totals mask the dynamics at work in different sectors of the prescription drug market. Spending on generic drugs has actually been declining, while spending on brands has been increasing. According to a November 2018 analysis, for the previous year, spending on brands increased 4% while spending on generics decreased 3%.[iii]

Further, the report indicates that while brand drugs made up only 17% of total prescriptions, they accounted for 79% of overall drug spending in the previous year.[iv]

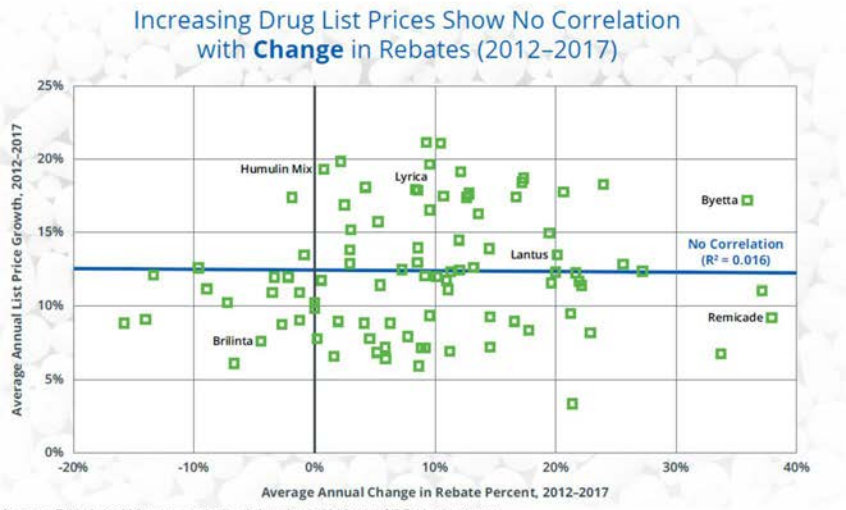
Data underlying the overall spending figures shows that manufacturers have been increasing the prices they set for their drugs rapidly. According to IQVIA data, for the five-year period ending 2017, brand invoice price grew at an average annual rate of 10.5%, while overall inflation in the economy, as measured by CPI-U, grew at an average annual rate of 1.3%.[v] These trends are mirrored in a study conducted on drugs most used by the elderly. A 2018 AARP analysis found retail prices for 113 chronic-use brand name drugs on the market since at least 2006 increased cumulatively over 12 years by an average of 214 percent, compared with the cumulative general inflation rate of 25 percent from 2006 to 2017.[vi]

The near-flat overall trend for spending on all drugs, despite rising prices and spending for brands, illustrates the work that PBMs do as advocates for patients and their client health plans to hold the line on prescription drug costs.

Drug Manufacturers Alone Set and Raise Prescription Drug Prices

As the Aging Committee continues its work with respect to prescription drug costs, one thing is clear: only manufacturers have the power to set or change prices. In recent years, brand manufacturers and their allies have attempted to deflect blame for the prices they set by blaming other parties in the drug supply chain,[vii] including pharmacies, PBMs, and wholesalers. While much has been said and written, research studies show that there is no correlation between the prices manufacturers set and the rebates PBMs negotiate with manufacturers.

A 2018 study found no correlation between the prices that brand drug manufacturers set for individual drugs and the rebates that they negotiate with PBMs on those products (see chart below).[viii] The data in the scatter plot below show that increasing list prices over a five-year period were not correlated with changes in rebates (R^2=0.016), as shown with the horizontal blue line. Additionally, there are prominent cases of higher-than-average price increases on brand drugs where rebates stayed the same or declined (e.g., Humulin).



Source: PCMA and Visante analysis of data from CMS and SSR Health, 2018.

At the same time, separate research confirmed that negotiated rebates are correlated with competition—that the size of drug rebates is positively correlated with the extent to which a given brand drug faces competition in the market.[ix]

Other research sponsored in part by a multinational brand drug manufacturing firm reports that, for every $100 spent in the drug supply chain on branded drugs, manufacturers capture $58. This contrasts sharply with the amounts captured by pharmacies ($3), PBMs ($2), and wholesalers ($1).[x] These results show that it is the manufacturers who benefit far more than any other party in the drug supply chain, and any rhetoric to the contrary is a smokescreen.

Further illustrating the lack of any connection of manufacturer list prices to negotiated rebates is the chart below containing Part B pricing data. Drugs under Medicare Part B typically carry no rebates. The chart shows that several unrebated branded drugs have posted price increases vastly outpacing the rate of inflation, as well as the rate of price increases among most drugs. Moreover, unrebated drugs in Medicare are not unique to Part B—HHS's Office of the Inspector General finds a full 39% of branded drugs in Part D carry no rebate.[xi]

Selected Part B Drugs with High Price Increases from 2017 to 2018

Brand Name	2012 Price per Part B prescription	Estimated 2017 Price per Part B prescription*	% Price Increase 2012-17	Estimated 2018 Price per Part B prescription*	% Price Increase 2017-18
Miacalcin	$461	$16,375	3,449%	$19,266	18%
Krystexxa	$2,717	$19,163	605%	$21,127	10%
Teflaro	$110	$399	263%	$439	10%
Bicillin	$41	$106	159%	$120	13%
Rituxan	$5,125	$6,890	34%	$7,416	8%
Orencia	$1,636	$2,849	74%	$3,020	6%

*Estimated inflation adjusted price = 2012 price * weighted average manufacturer increase in list price per unit. Not affected by changes in numbers of units per claim, or mix of doses/dosage forms. Estimated 2018 price through Q3 2018.
During study years PBMs were not involved in Medicare Part B program, so no PBM rebates were involved. Analysis included drugs with Part B spending data for full period 2012-16.

Source: Visante and PCMA analysis of data from CMS and SSR Health, 2019.

In sum, the research record is clear: drug manufacturers alone are responsible for the prices they set and neither PBM-negotiated rebates, nor any other party nor factor in the supply chain affects the list price of a brand drug.

Managing Drug Cost Growth Is Challenging, but Policy Changes Could Improve Competition

PBMs have an established record of negotiating with manufacturers and pharmacies to reduce costs for patients, either in the form of lower premiums for all participants in a plan, or through lower costs at the pharmacy, and usually both.

The key to reducing prescription drug costs is increasing and encouraging competition, for example, through polices such as those contained in the Biologic Patent Transparency Act, sponsored by Sen. Collins. PBMs are best able to negotiate when competition exists, and PCMA's member companies support a number of ideas for increasing competition and building

upon market-based tools to improve the Medicare Part D program, which is of special interest to the Aging Committee. These include:

- **Remove Part D's protected classes**. Designating "classes of clinical concern" where all or substantially all drugs in a class must be covered allows drug manufacturers to virtually name their price. Indeed, a recent Milliman analysis showed that the average brand rebate (for drugs that had any rebate) in Part D was 30%, while the average rebate for brand drugs in protected classes was 14%.[xii] CMS already applies careful plan formulary coverage checks to assure proper coverage. A pending CMS plan only to lessen the effect of protected classes—not eliminate them—would save $2 billion over 10 years.

- **Encourage greater use of generics for Part D LIS enrollees.** MedPAC recommended allowing the Secretary to lower cost-sharing on generics and raise it for brands that have generic competition. Allowing plans to lower generic cost-sharing for these beneficiaries would save money for beneficiaries, taxpayers, and the Medicare program.

- **Modify the requirement for two drugs per class.** The requirement that Part D plans cover two drugs per class is outmoded. It has encouraged manufacturers to argue for ever more granular classes and reduced competition, increasing Part D costs. Modifying the requirement by requiring plans to ensure access to therapies based on conditions or disease states instead would reduce costs without reducing access to needed drugs.

- **Build on existing efforts to apply Part D management tools to Part B drugs.** PBM tools such as value-based formularies, manufacturer negotiation, and prior authorization have proven indispensable for improving patient safety and lowering costs in outpatient prescription drug plans like Part D. Adding Part D management tools to the Medicare fee-for-service program and building on efforts in Medicare Advantage for Part B drugs would make drugs more affordable on Medicare's medical side.

- **Encourage use of mail-order pharmacy in Part D.** Mail-order pharmacy: vastly reduces errors in dispensing; increases convenience for beneficiaries on maintenance medications; improves adherence; and offers a lower cost-sharing option to beneficiaries in most cases. With much of the public using home-delivery for a wide range of goods and with many Medicare beneficiaries home-bound, CMS should take further steps to encourage home delivery of maintenance medications.

- **Inform patients when a drug is prescribed how much they will pay.** Patients would benefit from knowing at the time a physician prescribes a drug what their cost-sharing will be, based on where they are in their benefit structure (in the deductible, catastrophic phase, etc.) and the pharmacy they select. Providing this information through the use of real-time benefit tools (RTBTs) will encourage patients to make the most cost-effective decisions on their care.

- **Repeal any willing pharmacy provisions.** Requirements that all pharmacies be included in Part D networks drives up costs and are unnecessary, given the network adequacy requirements. Congress should repeal the provision. One study showed that greater use of limited network pharmacies in Part D could generate $35 billion in savings over 10 years.[xiii]

- **Give Part D plans meaningful access to Part A and B claims data.** To coordinate care and make the best coverage decisions for beneficiaries, plans need to be able to use

medical data as well as Rx data. Existing prohibitions on using A and B data to inform coverage design and decisions are misguided and keep plans from using claims data to improve care coordination and coverage. Researchers suggest combined data sets of Parts A, B, and D claims can be a "rich resource" for comparative effectiveness data.

The following list of additional solutions would further increase competition in the marketplace, which should help to bring balance back to the drug marketplace and enhance competition.

- **Eliminate use of Risk Evaluation and Mitigation Strategies (REMS) to delay competition.** Some manufacturers have used REMS to prevent generic or biosimilar developers from getting sufficient quantities of a drug or biologic to develop a competitor to the innovator product. REMS were never intended for this purpose; this practice should be prohibited. S. 340, "Creating and Restoring Equal Access to Equivalent Samples Act of 2019" or the "CREATES Act of 2019" would address these abuses.

- **Stop anticompetitive product adjustments, i.e., "evergreening."** Drug manufacturers sometimes use tactics such as "product hopping" or "evergreening," submitting applications to the FDA for approval of a "new" product that is essentially the same as the original product. These product lifecycle management tactics artificially extend drug exclusivity periods and delay the take-up of lower-cost generics.

- **End orphan drug exclusivity abuses**. Orphan drug exclusivities are meant to encourage research on rare diseases, but manufacturers have gamed the policy to apply it to blockbuster drugs with script volume in the tens of millions. Orphan exclusivity periods should only apply to those drugs originally approved by FDA under an orphan indication and only for the orphan indication itself.

- **Eliminate "pay-for-delay" agreements.** Patent settlements, or "pay-for- delay" agreements, allow drug patent holders to pay off potential competitors who would otherwise produce a competing generic or biosimilar drug. These anticompetitive agreements should be eliminated. S. 64, "The Preserve Access to Affordable Generics and Biosimilars Act" would greatly ameliorate these concerns.

- **Allow for FDA accelerated approval of brand drugs based on increasing competition.** Accelerated review is granted to new drug applications that address "unmet need." The economic need for competition to lower prices, or what some call "financial toxicity," should be a criterion of unmet need.

- **Revisit and improve biosimilar labeling and naming.** Substitutable biosimilars should bear identical names and labels to their innovator analogs. Use of different names will confuse patients and providers and inhibit prescribing of biosimilars.

- **Reduce innovator biologic exclusivity to seven years.** Seven years of data exclusivity would still provide a sufficient return to manufacturers, while also speeding more affordable biosimilars to market.

These policies and some of the specific bills that contain them can help lower costs in Part D and the wider prescription drug market.

Part D Should Work for All Enrollees, but the Administration's Proposed Rule Ending Drug Rebates Is Counterproductive

In addition to the suggested policy changes above, specific interventions to help Part D beneficiaries who have high out-of-pocket spending are needed. Fourteen years into the program, it remains a great success with high enrollee satisfaction. In fact, a 2018 enrollee survey echoes previous results showing that nearly 85 percent of seniors are satisfied with their Part D coverage and more than eight of every 10 are said their monthly premium is affordable.[xiv]

Nevertheless, policymakers should consider how best to balance the needs of all Part D enrollees, especially those with unmanageable cost sharing. With respect to the Administration's recently proposed rule to end the drug rebate safe harbor, however, there is grave concern that this proposed rule would increase premiums for Medicare beneficiaries and costs for taxpayers.

While the Administration's goals are well intentioned, the proposed rule does nothing to reduce the prices drug manufacturers set. To the contrary, it would cause substantial increases in seniors' Part D premiums, as well as the cost to taxpayers.

The Administration's proposal also includes an unprecedented six different cost impact estimates by three different actuarial groups, including the independent HHS Office of the Actuary (OACT). The range of impact for cost to the federal government across the six estimates is an immense $300 billion. The great uncertainty surrounding the proposal should give the Committee pause. Americans deserve clarity on how such a proposal will affect those who rely on Medicare and Medicaid, and commercial coverage. Given OACT's skill and institutional independence from the agency, it is likely they have the most accurate estimates.

Under the Administration's proposal, according to OACT, Part D premiums could rise by as much as 25 percent for 2020 to reach $47.66, marking the largest average premium increase in the program's history. Such a large increase could cause many seniors and disabled Americans to drop the prescription drug coverage they need to protect their health and financial security, or never sign up in the first place. Healthier beneficiaries (i.e., those who need fewer drugs) would drop coverage first, causing premiums to increase further and potentially destabilizing the Part D program, as increasingly those eligible for enrollment would find Part D coverage unaffordable.

Additionally, OACT estimates that the proposal would cost the federal government an extra $196 billion over the next 10 years. If finalized, this could make the proposed rule among the costliest in U.S. history.[xv]

PCMA urges the Aging Committee to encourage the Administration to withdraw, or at the very least significantly delay the implementation of, the proposed rule until its impact on beneficiaries and on Part D can be better understood and managed.

Conclusion

In the search for solutions to address high drug costs, the Aging Committee and all of Congress would be best served in pursuing policies that foster and encourage competition to keep prescription drug costs and pharmacy benefits more affordable for employers, enrollees, taxpayers, and government programs. Unfortunately, the rule recently proposed by the

Administration will not accomplish this goal, since it does nothing to encourage manufacturers to bring down the drug prices they alone set.

PCMA member companies welcome continuing discussion among all stakeholders to create a robust, sustainable market that will continue to deliver needed cures and treatments for patients who suffer through disease and chronic illness.

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[i] Visante, "Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers," February 2016. https://www.pcmanet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf

[ii] KFF, "What Are the Recent and Forecasted Trends in Prescription Drug Spending?", February 20, 2019. https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-start

[iii] Blue Cross Blue Shield Association, "Prescription Drug Cost Trend Update," November 14, 2018. https://www.bcbs.com/the-health-of-america/reports/prescription-drug-costs-trend-update

[iv] BCBSA, Op. Cit.

[v] https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022

[vi] AARP, "No End in Sight for Skyrocketing Prescription Drug Prices," September 26, 2018.

[vii] See, e.g., https://www.phrma.org/press-release/new-report-shows-how-supply-chain-shapes-brand-name-medicine-prices

[viii] Visante, "Increasing Prices Set by Drugmakers Not Correlated With Rebates: An Analysis Prepared by Visante on behalf of PCMA, June 2017

[ix] Credit Suisse Equity Research, "Global Pharma and Biotech," April 18, 2017

[x] Sood, N. et al. "The Flow of Money through the Pharmaceutical Distribution System," University of Southern California, Leonard D. Schaeffer Center for Health Policy & Economics, June 2017. https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC_Flow-of-MoneyWhitePaper_Final_Spreads.pdf

[xi] HHS Office of the Inspector General, "Increases in Reimbursement for Brand-Name Drugs in Part D," June 2018.

[xii] Milliman, "Prescription Drug Rebates and Part D Drug Costs Analysis of Historical Medicare Part D Drug Prices and Manufacturer Rebates," July 16, 2018. https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Part-D-Rebates-20180716.pdf

[xiii] Visante, "How Pharmacy Networks Could Save Medicare, Medicaid, and Commercial Payers $115 Billion," January 2013.https://www.pcmanet.org/wp-content/uploads/2016/10/visante-pcma-pharmacy-networks-study-1-13.pdf

[xiv] Medicare Today, "Senior Satisfaction Survey," August 2018. http://medicaretoday.org/wp-content/uploads/2016/07/8.21.18-Senior-Satisfaction-Survey-Fact-Sheet.pdf

[xv] American Action Forum, "Mandating Talking Cars: Costliest and Most Beneficial?," December 16, 2016. This article describes what were at the time, the two costliest proposed regulations in U.S. history. The OACT cost estimate for the Administration's proposal is in excess of these two. https://www.americanactionforum.org/regulation-review/mandating-talking-cars-costliest-beneficial/

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